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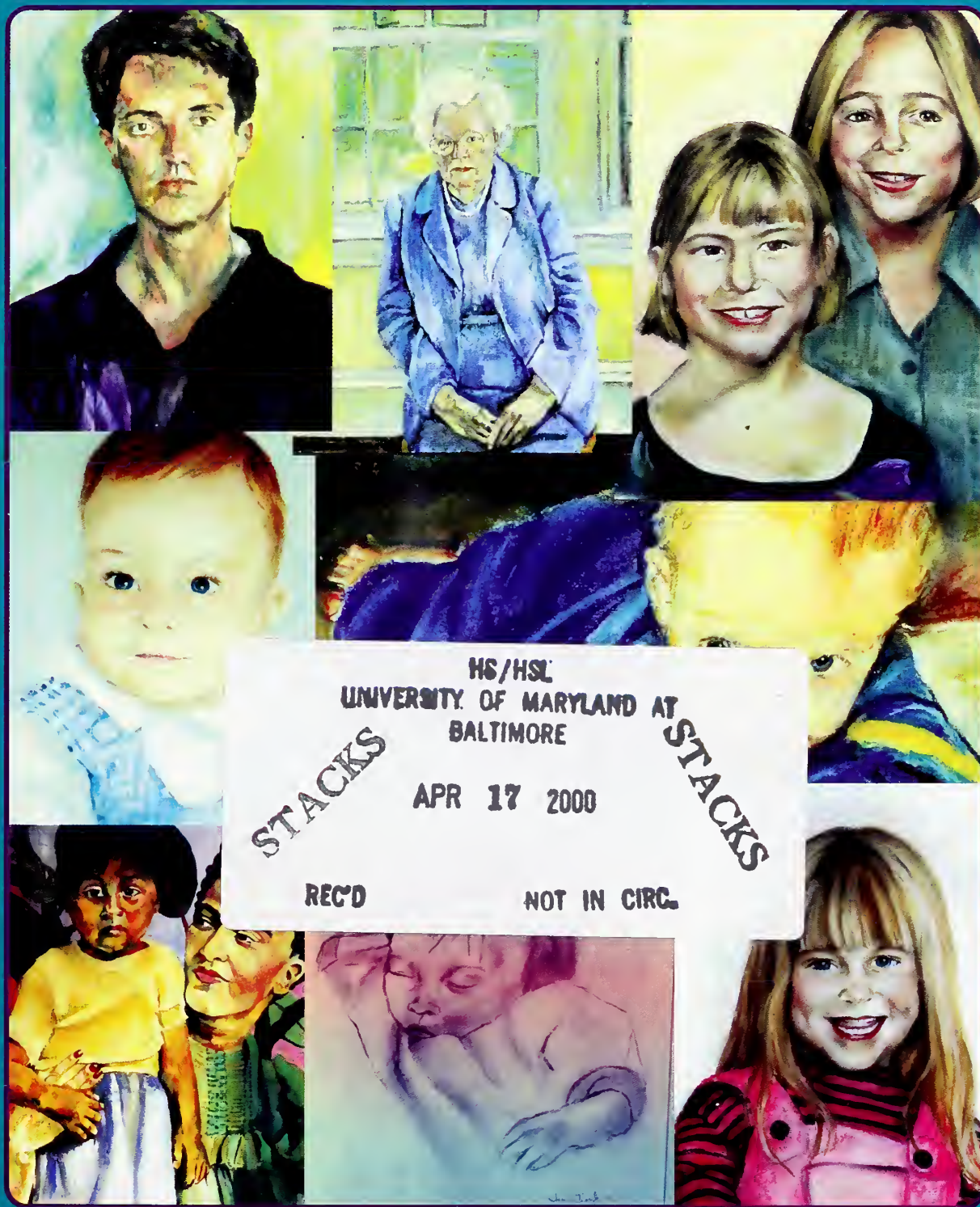
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Medicine AND Health RHODE ISLAND

VOL. 83 No. 1 JANUARY 2000



Family Medicine

An open letter to Rhode Island physicians

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Warm regards,



Christine C. Ferguson
*Director, RI Department
of Human Services*



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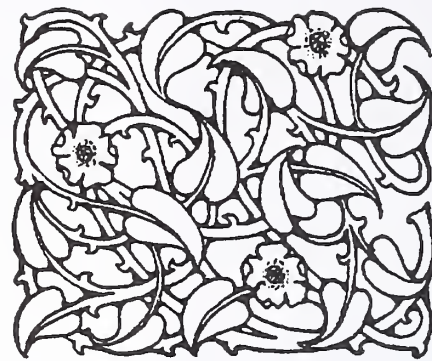
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Specialists and the Current Medical "System"



This issue devoted to Family Medicine is a perfect venue to address the issue of the primary care-specialist relationship. Dr. Long, in his apology and call for collaborative support in obstetrics, and Dr. Fine, in his essay on medical systems' structure address this topic from the primary care provider's (PCP) perspective.

I am a neurologist and therefore on the other side of the looking glass. Like other specialists I have been concerned with the inroads medical insurers have made on the freedom to obtain consultations. Many years ago when "primary care" was an emerging buzzword, many specialists, especially in the areas outside of "traditional" internal medicine (eg infectious disease, cardiology, etc) thought the shift from specialized to primary care would lead to increased referrals due to the decreased numbers of specialists. This does not seem to have occurred. An abstract at the October American Neurological Association's 1999 meeting may have addressed one aspect of this issue. From a mailed survey to 624 general internists in the American College of Physicians- American Society of Internal Medicine registry and 492 neurologists in the American Academy of Neurology in which opinions were asked about obtaining neurological consultations for three clinical case sce-

narios, the following data emerged.

* For a case of Parkinson's disease 53% of internists and only 10% of neurologists believed the PCP should manage the case without a consultant's input.

* For a case of late onset dementia 80% of the PCPs and 5% of neurologists thought the PCP should manage the case alone.

* And for a TIA 73% of PCPs and 7% of neurologists thought the PCP should manage the case alone.

These numbers tell us either that neurologists believe they provide a much more important service than their referral sources do, or that PCPs do not know their limits, or something in between. There are lots of jokes on the uselessness of neurologists and the advent of sensitive brain imaging has altered much of what the neurologist had, until recent times been asked to do (I am reminded of a time when brain tumors were localized clinically. In a presumably true but apocryphal story, a famous neurosurgeon chose to ignore the determined opposition of his equally famous neurologist for choosing the operative site. When the neurosurgeon was found to have chosen correctly, the crushed neurologist muttered, "I'll have to give up neurology now!" To which the neurosurgeon replied, "on the contrary. Why not take

it up?") and although our treatments are rudimentary at this time, there are an increasing number of neurological disorders that can be treated, but this often requires expertise.

As the number of specialists slowly dwindles with the cutbacks in training programs there will be no choice but to charge the PCP with more responsibility for diagnosis and treatment. Finding appropriate limits for medical consultations is crucial. In addition, many specialists necessarily take on a primary care role for patients afflicted with incurable disorders such as ulcerative colitis, Parkinson's disease, and rheumatoid arthritis. Should the specialists only provide consultation or should they be the primary manager of "their" disorders? I know what I would want for myself as a patient. The gatekeeper concept is one control mechanism but it puts physicians in an adversarial role with their patients. Having in place strictly defined criteria for referral is easier on the PCP but are impossible to develop in a meaningful way.

Working out this delicate balance is a crucial problem facing all health insurance programs. Simply reducing the number of specialists, which is the current nation-wide approach, will probably work no better than most government - rationed programs. Physicians need to develop a model for the efficient integration of primary and specialty services that maximizes the quality of care and exploits fully the available skills within our profession. Unfortunately this doesn't seem to have been accomplished even in those HMOs that were initially developed by physicians themselves.

— Joseph H. Friedman, MD

THIS COMING YEAR IN *Medicine & Health/Rhode Island* one popular column will be missing: John Tierney will no longer be contributing Medical Philately. In February 1996 when John began the column, he noted, "The experience [of medical philately] increases one's knowledge and understanding of the history of medicine, especially about those gifted ones whose dedicated genius has led to the lengthening of our life span." Many readers will concur. All of us at the *Journal* - editors, writers, and readers - are thankful to and for John Tierney, and wish him well.

The Evils in the Forest Primeval

Once, long ago, there were great forests, home to vast numbers of contending vertebrates, invertebrates and micro-organisms. These forests were sites of uncompromising struggle where the grim business of survival, uncomplicated by moral judgment, was pursued without abatement.

Prompted in 1906 by an expanding population and an increasing need for more rapid lines of communication, the government of Brazil elected to build a railroad line from Rio de Janeiro north to the Amazon delta port of Belem traversing the vast virgin forests of Minas Gerais, crossing the Planalto, contending with hostile Indian tribes, and intruding upon the unmapped interior forests of Bahia and the provinces south of the Amazon river.

The initial miles of the new railroad proceeded without significant mishap or delay. But by 1908 things were going badly. The health of large numbers of laborers, mainly Africans, began to fail. Many died of diseases, known and unknown, while thousands were left too weak to continue the arduous work of bringing a rail line through the tropical wilderness.

The Central Railroad of Brazil then invited Dr. Carlos Chagas, a 31 year-old public health physician and a recognized authority on the control of malaria, to determine the nature of the many illnesses burdening the workforce. Chagas arrived at the small frontier town of Lassance and was given two freight cars, one to be employed as a hospital and one as his provisional residence and laboratory. The town was little more than a makeshift place with thriving bars and brothels to service a working cadre of about two thousand men. Malaria and syphilis were rampant; but for these illnesses Chagas had remedies. It was another illness, however, that puzzled him. This illness started suddenly with steady fever, a rash perhaps, excessive fatigue and various cardiac abnormalities. Most recovered the acute phase but were left with a lingering fatigue, loss of appetite, progressive heart disease and inability to work any longer.

Chagas visited the dwellings of the workers seeking some clue as to the cause of this unnamed illness. He observed that a large beetle, locally called *barbiero* or *vinchuca*, emerged in large numbers after sundown. They sought out those asleep, either humans or domesticated animals, and bit them, extracting substantial amounts of blood. Chagas captured many of these nocturnal blood-sucking creatures and found, after much dissection, microscopic parasites confined to their gut. These parasites closely resembled the trypanosomes of African sleep-

ing sickness. It was only after finding similar parasites in the blood stream of acutely ill humans that Chagas considered the organism as the likely causative agent of the unnamed illness. The final step in the proof came when Chagas and his mentor, Professor Oswaldo

Cruz, transmitted the disease experimentally to laboratory animals.

But how did the blood-sucking beetle manage to transmit the infectious agent since the organism was confined to its lower gut? Again, Chagas relied upon the simple art of diligent observation. He watched, night after night, as these beetles emerged from their nests in the crevices of the adobe huts of the workers to seek out their blood-meal. Chagas observed that the beetles reflexly defecated after each blood meal and that the patient then unconsciously scratched the bite invariably rubbing the insect droppings into the fresh wound.

Chagas reported his findings of the illness, now called Chagas' disease, to the scientific world in 1909. The parasite was named *Trypanosoma cruzi* in honor of his teacher, Professor Cruz. Alerted Latin American physicians now quickly found large numbers of cases in their territories. And field epidemiologists were able to demonstrate that the disease afflicted many forest vertebrates, domesticated animals and urban rats. The human infection was confined principally to the poorest elements of society, those whose homes harbored the *vinchuca* beetles which were the primary vectors of the disease.

Paleontologists then demonstrated that occasional Andean mummies from as early as 400 AD showed evidence of Chagas' disease. The illness did not become endemic to Latin America, however, until human settlements encroached upon the great tropical forests of South America, the natural home of the *vinchuca* beetles [technically called triatomes.] It now appears that the disease was first limited to those frontier villages at the interface with the cleared forest; but then, as the forest mammals [the usual source of blood meals for the *vinchuca* beetles] fled from the clearings, the beetles sought out humans and their domesticated animals for their necessary blood-meals. Both the beetles and infected rats then spread beyond the frontier towns to bring the disease to urban populations.

While beetle bites are the principal means by which the disease is spread, there are two additional pathways of significance: first, transfusions using contaminated blood. [In Brazil, about 15,000 transfusion-initiated cases of Chagas' disease arise annually.] And second, infected mothers may transmit the disease through the placenta to their unborn offspring.

The disease is currently managed by the use of residual insecticides. Yet, in impoverished Bolivia, for example, about one-fifth of the population suffers from the chronic form of Chagas' disease. There are an estimated 15 million cases in Latin America.

Triatome beetles have now spread to the southern states of the United States. And with the arrival of thousands of western hemisphere immigrants with chronic Chagas' disease, the stage is set for its indigenous transmission. The US Public Health Service has



already detected sporadic cases in Texas and neighboring states.

A 26 year old dilettante biologist with a fascination for beetles once explored the interior of Argentina by foot. And in his diary, dated March 26, 1836, Charles Darwin described the avaricious *vinchuca* beetles. Out of curiosity to see how they sucked up blood, he allowed many of them to bite his finger repeatedly. Darwin's chronic debilitating illness in later life is now presumed to be the persistent variant of Chagas' disease.

As humans intrude upon the forests, they may confront unanticipated biological and microbiological hazards. There is now adequate proof of the sylvan origins of yellow fever, sleeping sickness and Chagas' disease. And scientists studying the HIV diseases of African monkeys, now speculate that human AIDS once began as a jungle infection initially confined to primates such as old-world monkeys. Advancing the frontiers of civilization has its risks.

— Stanley M. Aronson, MD

Introduction: A Potpourri of Family Medicine

Stephen Davis, MD

"Family Medicine is nothing if not broad," begins Michael Fine's article in this edition of *Medicine & Health/Rhode Island*—this edition which is designed to demonstrate some of its breadth. Dr. Fine (with his wife Carol Leavitt, MD) has been involved with Family Medicine as a practicing family doctor presently in Rhode Island and formerly in the mountains of northeastern Tennessee with the National Health Service Corps.

He writes about the relationships between the primary care physician and the specialists with whom they are necessarily and (hopefully mutually) beneficially involved. Primary Care physicians in general and Family Physicians in particular are horizontal specialists; that is, they deal with aspects of medical care across the scope; their specialist colleagues, in contrast, are vertical specialists, developing and practicing their expertise in one area as much as possible. As such there is potential overlap, and overlapping responsibilities and roles may produce conflicts. Michael discusses how some of these conflicts may occur, may be exacerbated by third-party forces, and how they may be considered and resolved.

Patricia Nolan, MD, well-known to readers as the Director of Rhode Island's Department of Health, is not a

family physician but began her eminent career with an interest in primary care. She discusses the importance of primary care to preventive medicine.

Joanne Wilkinson, MD, a Rhode Islander born, raised, educated at Brown, educated at Brown some more, trained at the Memorial Hospital of RI, and now, at long last, a practicing family doc in Pawtucket, has contributed two first-person essays derived from experiences as a new attending. These experiences are from different ends of the life span and from contrasting expectations, but they both demonstrate the concern, the pathos, and the personal involvement that characterize a good family physician. Her description of the "family coming together" at a breathless pace is breathtaking.

Sarah Aronson, MD, the third member of that gifted family to grace these pages, has contributed some musings on Family Medicine and Psychiatry from her perch in Erie, Pennsylvania. These musings are not of the form such that "You'd have to be crazy to be a family doctor," but rather they are considered opinions from Sarah's almost unique perspective as one who has completed both a residency in Psychiatry (at Yale) and one in Family Medicine (at Middletown, Conn.). Recognizing the frequency of psychiatric and behavioral diagnoses in primary care, she gives us an orderly framework of care.

Rick Long, MD, has written a treatise discussing the often-controversial

phenomenon of family physicians practicing obstetrics. As a Family Medicine residency graduate, as a former 2-year fellow in Maternal Child Health Care at Memorial Hospital, as a residency faculty member supervising obstetric training, as co-director of the present Maternal Child Health Fellowship, as an Advanced Life Support in Obstetrics-certified instructor, and as an obstetrics-practicing family physician with many a cesarean section notched on his scalpel, he is familiar with the topic of which he writes. It is also a good example of a family physician developing an area of expertise, a frequent occurrence that is not otherwise discussed in these pages.

Dr. Isaih Malaprop, not a Rhode Island family doc, but rather an embodied amalgamation of the experiences of various colleagues, makes an appearance on these pages. This essay is reminiscent of an essay from the June, 1993 *Medicine & Health/Rhode Island* issue, the forerunner of this journal, which was devoted to Family Medicine. That essay, "A Day With a Family Physician" was a recounting of the variety of patients seen by one R.I. family doc in part of one day. This article by the same chronicler emphasizes a different aspect of a family doctor's experience, that of communication.

In addition, because the recent withdrawal of Harvard Health has sparked a crisis among patients, physicians, and hospitals, we have included an especially timely article by Max Powell, Leslie Tucker, and Nisha Lodhavia. The authors describe the "predatory pricing" that can force health insurers close to insolvency.



Family Medicine, Generalist Medicine, Specialist Medicine and the Conduct of the Consultative Relationship

Michael Fine, MD

Family medicine is nothing if not broad. Generalist medicine requires some special skills because of that breath, skills which are particularly necessary in a country without an organized health care system. In the absence of a formal system of health care services distribution, all generalists learn to create mini-health care systems around themselves, creating islands of health security for their patients.

Family physicians and other generalists prize their relationships with their specialist colleagues. These relationships allow us to improve the quality of care we can provide disease-by-disease and organ system-by-organ system. Relationships with consultants also provide a constant source of patient-by-patient continuing medical education.

The emergence of managed care as a major (if temporary) system organization has changed some elements of the consultative relationship. In this paper, I will reflect on those strains, trying to decipher what underlies them. I will argue that we can sort out conflicts by drawing a distinction between skills and roles, and I will highlight two competing theories of health care system organization that may also be creating disharmony in the consultative relationship. Finally, I will argue that only the collaborative approach allows us to address the demands society places on its medical community as a learned profession.

THE GATEKEEPER BLUES

One of the more frustrating aspects of the managed care era has been evolution of HMO gatekeeper procedures, which exploit primary care physicians to manage a process of matching resource to need for individuals that the society (as a whole) has been unable to do for itself as a whole. "Gatekeepers" are frus-

trating for specialists, because they add bureaucracy to the patient-physician relationship, and restrict specialists' clinical freedom, putting functional oversight in the hands of primary care physicians who may not have the same depth of knowledge about specific disease processes that their specialist colleagues have. These procedures are frustrating as well for primary care physicians, both because their side of the bureaucratic process is complex and needlessly time consuming, and because the gatekeeper system often draws primary care physicians into accepting some responsibility for the oversight of care where they have little or no expertise or interest.

But, as marketplace approaches to social problems often do, the gatekeeper HMO approach allows entrepreneurs to profit from implicit conflicts in power relationships between contending market forces. Here, the market has uncovered a conflict between primary care physicians and specialists in terms of the nature of the service each group delivers. It has also discovered a vestigial, implicit hierarchy in the health care system, and has used that hierarchy to counter the adverse economic effects of the application of the free market to the distribution of health care services. The market is implicitly challenging assumptions about how the health care system should be organized, assumptions that are so deeply held that they may not be apparent to the participants in the system.

WHAT IS THE ROLE OF THE PRIMARY CARE PHYSICIAN?

Primary care physicians build and maintain relationships with people in their communities over time. Primary care practices use that relationship to provide people access to the health care system when they need it, to help them manage chronic health conditions, and to help those with multiple medical

Abbreviations Used:

HMO	health maintenance organization
LMD	local medical doctor
PCP	primary care physician

problems balance the subsequent contending management needs. Primary care physicians' skills include diagnosis and treatment, palliation of symptoms that do not require further diagnostic evaluation, the ability to identify areas of concern that require further diagnosis and treatment, and a thorough knowledge of the health care systems' function, so that identified areas of concern can be most efficiently addressed elsewhere in the health care system. Despite these skills, relationship is the center of the primary care physicians role in the system. It is relationship that makes the PCP primary to the patient, and relationship that makes the PCP critical in adapting the world view and needs of the health care system to the world view and needs of the patient, so the patient can benefit from what the health care system has to offer.

WHAT IS THE ROLE OF SPECIALTY PHYSICIANS?

Specialty physicians excel at the diagnosis and treatment of specific diseases, and at the ability to confirm the absence of specific diseases that are being considered as part of a diagnostic evaluation. Specialty physicians skills also include maintaining relationships with patients over time, palliation of symptoms that do not require further diagnostic evaluation, the ability to identify related areas of concern that require further diagnosis and treatment, and a knowledge of much of the health care systems' function, so that identified related areas of concern can be addressed elsewhere in the health care system.

SKILLS AND ROLES

The overlap in skills between primary care and specialty physician produces most of the conflict in the system between the two groups, with flashpoints occurring around gatekeeper referrals, hospital privileging issues, and allocation of scarce resources. The logical distribution of roles, on the other hand, points a way to resolving those conflicts, to the extent solutions to those conflicts can be negotiated between physicians in a way that respects and reinforces those role definitions.

TWO THEORIES OF HEALTH CARE SERVICES DISTRIBUTION

The tension that exacerbates conflicts in the relationship between primary care physicians and specialists is the one that exists between two contending theories of health care services distribution. Most observers argue that health care services in the United States use the free market model, in which each physician is a purveyor of a service who seeks to maximize her or his own profit by identifying need for and selling as much of that service as possible. In this model, we generally measure service in units of encounters and procedures, so that each physician attempts to provide (and thus sell) as many encounters and procedures as possible in the shortest possible time. Free market medicine allowed physicians to achieve unprecedented financial security, but that prosperity came at great cost to the nation. Health care costs rose to greater than 14% of the gross domestic product - a percentage that presumably threatened to undermine the nation's competitiveness in the emerging world market.

To control those costs, the marketplace turned to another theory of health care services distribution. Most health care systems balance the roles of specialists and primary care physicians, using primary care physicians to establish locally based access to a large proportion of the population, and specialists to provide expert diagnosis and treatment to the relatively few ill people who need those services, usually by concentrating those services at a central site in order to achieve a critical mass of patients with diseases that require specialty attention. The concept of the LMD (local medi-

cal doctor) is evidence that this hierarchical system has existed in an informal way in the United States. Managed care companies exploited the implicit hierarchy with their distribution of roles, formalizing something for physicians that physicians had not chosen to formalize for themselves. But that formalization provoked a conflict between specialists and primary care physicians, as primary care gatekeepers found themselves agents of managed care companies' interest in limiting expenditures, and thus reducing specialty physicians incomes.

*Primary care physicians
build and maintain
relationships with people
in their communities
over time.*



Despite managed care organizations' actions to make the role structure of specialists and primary care physicians explicit, that role structure may contain something of value. Specifically, a hierarchically organized health care system that defines the complementary roles of specialists and primary care physicians may be in the interest of the medical profession itself. Society looks to the medical profession to provide both exquisite care of individuals and a secure system of care for the society as a whole. An enlightened understanding of our complementary roles allows us to provide that secure system of care, which is impossible if we see ourselves as competitors in a marketplace.

In addition, understanding our complementary roles allows for a fair amount of mutual assistance in addressing the responsibilities placed on us by the burden of illness. If specialty physicians had to answer all the system-oriented complaints (many of which arrive in the middle of the night) from each person with a symptom in their specialty area, they would get no rest. If primary care physicians had to know everything about the diagnosis and treatment of every disease or condition that exists in patients under their management, we

would spend our lives in the medical library and have no time to see patients.

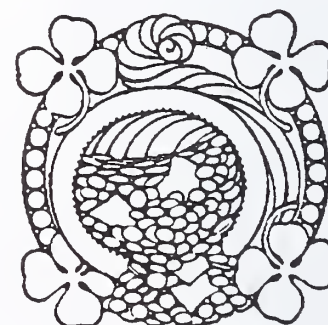
CONCLUSION

Despite the tensions that marketplace medicine have placed on the relationship between generalist and specialty physicians, a focus on the complementary roles of generalist and specialty physicians allows the medical community to address both the needs of exquisite patient care and society's requirement that we create a secure system of care. A hierarchically organized health care system may not allow individual physicians the ability to maximize their economic situations, but that is not the primary role of a learned profession. Working together to create a more formally defined health care system with one set of rules and one network of providers may simplify the relationship between specialists and generalists, but the path to such system organization is not clear. There is no consensus about the wisdom of organizing such a system, nor is there consensus about the structure of this system, or its modus operandi. Still, a focus on the complementary roles of primary care and specialty physician allows a more successful negotiation of the conflicted world the market has placed us in, and may help us attend to the work at hand, which is providing both excellent patient care and a secure system of care for the society as a whole.

Michael Fine, MD, is President, Rhode Island Academy of Family Practice, and President, Center for Occupational and Environmental Health of Rhode Island.

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Primary Care: The Backbone of Prevention

Patricia Nolan, MD, MPH

Primary care physicians are critically important in reaching public health goals in Rhode Island. We turn to them to provide care for low-income patients under RItE Care, to immunize our children, to guide the care of persons with diabetes, hypertension, heart disease, and hundreds of other chronic conditions. We ask them to promote and encourage prevention strategies, from smoking-cessation and walking to safe sex.

The Department of Health advisory group, the Primary Care Physicians' Advisory Committee, brings us advice from the primary care physicians in this state. The strong message from this advisory group is that we must pay more attention to the needs of primary care physicians if we expect them to function effectively.¹ Our loan repayment program is finding fewer candidates among primary care physicians because many choose to leave Rhode Island after their training is completed. From some perspectives, Rhode Island appears to have enough primary care physicians, yet these physicians are frustrated by what they perceive are low payment rates from insurers in the face of escalating demands for administrative processing, clinical efficiency, and preventive interventions. The Primary Care Physicians' Advisory Committee is consistently reminding us of the system's problems we have to solve to have effective primary care for the people of the state.

CLINICAL PREVENTION IN PRIMARY CARE

The *Guide to Clinical Prevention Services* is intended for primary care clinicians. It provides recommendations for clinical practice of preventive interventions - screening tests, counseling interventions, immunizations, and chemoprophylactic regimens - for the prevention of more than 80 target conditions."² Of course, all of you have had time to read and digest these 1000

pages, and its companion, *Health Promotion and Disease Prevention in Clinical Practice*, and have put these science-based interventions into practice during the past three years. This valiant effort at making the latest science available and into practice is weighty, but we do know that remarkably busy practitioners do incorporate clinical prevention strategies into practice. Emphasizing prevention in primary care practices does help your patients avoid preventable illnesses.

The Rhode Island Department of Health has identified a number of prevention actions that we encourage primary care physicians to integrate into clinical practice. This article describes several of these strategies.

The Department of Health advisory group, the Primary Care Physicians' Advisory Committee, brings us advice from the primary care physicians in this state.



IMMUNIZATIONS

Immunizations for infants and children have been a success. Rhode Island ranks among the top few states in the percent of two-year-olds with completed immunizations. When the meningitis panic hit in February, 1998, the primary care community assured that the vast majority of children in the state received immunizations.

Physician adoption of adult immunization strategies has been less complete, with low rates of influenza, pneumococcal and diphtheria-tetanus immunizations among the target groups.

Immunizations are increasingly effective, preventing a wide array of

Abbreviations Used:

ETS	environmental tobacco smoke
-----	-----------------------------

bacterial and viral infections, and being delivered on an increasingly complex schedule. The Department has explored two new strategies to improve immunization levels among target groups: computer support systems and office materials.

Kids Net serves as a computerized immunization registry, providing access to health data on a child and offering reminder/recall functions. As more physician practices participate, Kids Net will become a more useful tool, since the data is available to physicians caring for a child. Kids Net includes other important data and soon will contain the same features for the newborn metabolic screening data. The success of this effort will be measured in two ways: by our maintaining or increasing immunization rates, and by the level of acceptance of participation in the Kids Net system. Our participants tell us that Kids Net needs to be web-based and simpler.

Office materials for adult immunizations have been developed through the Ocean State Adult Immunization Coalition. The coalition seeks to increase the rates of adult immunization, combining public information, professional information, and feedback on levels of immunization. Tool kits containing posters, patient brochures, reminders and physician information on the vaccines were distributed to primary care physicians this fall in an effort to increase the number of adults over 65 or with chronic illnesses who receive appropriate immunizations. The penetration of influenza and pneumococcal immunization in the Medicare population will be used to measure success. Between 1996 and 1997, we increased the rate of influenza immunization for people over 65 by 2.1%, but remain under 50% coverage at 49.8%.

BREAST AND CERVICAL CANCER SCREENING

The Department of Health has been an active participant in federally funded efforts to increase breast and cervical cancer screening, especially among older women and women in ethnic and language minority groups. Breast cancer rates in Rhode Island are above the rate for the United States as a whole, and are particularly higher among African American women.

MORTALITY RATES⁵

Mammography for the earliest possible detection of breast cancer has proven utility in preventing deaths. Women, especially older and minority women, are not all tuned into the importance of regular screening mammography. One reason given for not seeking mammography has been that "my doctor did not recommend it".⁵ When we began this project, we organized regional resource centers to do outreach to women to get them signed up for mammograms. We gradually realized that the centers were too disconnected from the physicians. We have revised our strategy to focus on the primary care physician as the instigator of screening mammography, and tried to provide the physician with support for referrals of low-income women and others who are hard to reach. The experience with immunizations has demonstrated the value of reminder/recall strategies to initiate periodic interventions. The use of reminder/recall systems can greatly increase the appropriate interval use of pap smears and mammography and save lives.

TOBACCO CESSATION AND PREVENTION

Primary care physicians are constantly dealing with the health consequences of tobacco use. The Department of Health employs many strategies to reduce tobacco use, especially counter-advertising and peer group anti-tobacco support. We are encouraging health plans to cover tobacco cessation as medically necessary care, and to increase the offering of cessation counseling to smokers. Management systems should include reminders to notify the physician to re-check smoking status on every visit, and simplified referral to smoking cessation services.

There is increasing interest in the effect of environmental tobacco smoke (ETS) on fetal development, infant airway development, and childhood respiratory diseases,

especially asthma. We need to communicate with all members of households with pregnant women and small children about the importance of reducing ETS exposures. Primary care physicians, including obstetricians, can address this issue. Part of our task as a health department is to help you connect your patients with cessation services and to encourage their insurance plans to pay for those services. Asking your patients whether there are pregnant women or small children in the household, and then inquiring whether there is smoking in the home, provides an excellent starting point. However, the primary care physician then needs to be prepared to take the next step in cessation, and that becomes a more complex algorithm. We are now exploring ways to simplify that next step.

CONCLUSION

Primary care physicians are critically important in reaching public health goals in Rhode Island. Therefore, the Department of Health is seeking a more effective partnership with them. Through the Primary Care Physicians Advisory Committee, we are listening to the concerns of primary care physicians and seeking solutions to problems. These concerns are circulated throughout the Department in an effort to develop strong working partnerships, and to address regulatory and administrative barriers to the adoption of prevention strategies in primary care.

The Department is open to new strategies to enable primary care physicians to incorporate prevention into practice. This paper discusses several strategies already adopted in Department programs.

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Reflections from the Field

Joanne Wilkinson, MD

Baby

Push, now push, hold it you're doing great I say, and with my right hand fumble for the sterile towel, laid out kelly green like a dishcloth on the table of gleaming steel. Something is trying to happen, I see the onslaught of inexorable movement beginning deep inside, feel the hard slippery head turning against my gloved fingertips. There is a moment when I know before the mother does, I see the clenched-up muscles begin to let go, I realize this push will be the last and I say okay, now with that next contraction I want you to push long and hard, and you'll feel a lot of burning and stretching and pressure and I want you to keep pushing right through all that, even though it hurts, because you're almost done, I promise you, this is really it. And she nods, sweaty, pale, my patient, whom I have known since I was an intern and she was a high-school student, whom I have laughed with and soothed and explained things to, who brought her pink EPT to the office so I could see, and we talked about baby names and the advice from her mother-in-law, palpated her belly and felt the life inside kick back to me, over and over, until I am almost as impatient as she is to finally meet this other being, to hold it, at long last, in my hands.

Okay, now this is it, big push big push and she contorts her face, she grimaces with her mouth but her eyes never leave mine, she won't look away now, in the throes of pain she is almost unrecognizable to me but the eyes shine dangerously, determined, sparking back the light from the portable lamp that is warming my hands. See the baby's head, I say to her husband, whom I have reassured and talked to and teased over the past eight months, and he looks down at my hands with a scared and fascinated expression, like a passing motorist at a gory accident, unable to look away. And now there is pressure, there is screaming, there is an explosion of flesh, and I

*... just for a moment I
am at the center of your
existence, the first one to
hold you, to dry you off
while your parents stare
in disbelief that they
have done this, that they
are done.*



lose track of everyone for a moment, the patient the husband the nurse, I pull gently on the little one in a moment of total concentration, slack-jawed, unconscious, the seconds stretching out and then suddenly, I am snapped back to myself, a warm slimy infant clasped across my chest, the heat sensor on the baby monitor going off in the background, the agitated voices all babbling at once, and the little mewling cry. The forehead wrinkles, the left arm jerks, the mouth makes petulant shapes and I think I know you, little one, I have studied you from afar like a cultural anthropologist and now you are here, and just for a moment I am at the center of your existence, the first one to hold you, to dry you off while your parents stare in disbelief that they have done this, that they are done. The skin pinks, the eyes open and shine and I cut the cord, neat and clean, like always, and I say there you go sweetie, why don't you go see your mom, and at the word mom my patient's face changes, softens, realizes and she reaches like she already knows this baby, knows where it belongs. And she reaches, and I reach, our arms overlapping as I put the baby in hers, and then I step away, gently untangling our hands, breathing as the family comes together before my eyes.



Abbreviations Used:

EPT	early pregnancy test
CPR	cardiopulmonary resuscitation
DIC	disseminated intravascular coagulation
ER	emergency room
ICU	intensive care unit
IV	intravenous

The ICU

These are the things I usually say to someone who is dying: We're all here with you. Breathe in and out. Good Job. Any pain? No? Good. Can you feel my hand? Great. I'm right here next to you. I won't leave, I promise. Sometimes I say soothing things like There you go, that's good, just close your eyes, I'll be right here. By then they are usually unconscious, and I know they're never coming back to tell everyone all the stupid, unprofessional things I said, and I just open my mouth and say what seems right. But not this lady. This lady is awake.

When I admitted her to the ICU, at lunch time, things didn't look so bad. I rushed over from the office when the ER called and said they had my partner's patient, a woman in septic shock; they were giving IV antibiotics, putting in a central line, but she was awake and talking. When I went to meet her she was looking critically at the clean plastic dressing covering her IV site and telling me that there was a spot of blood on her arm, and it looked dirty. I thought: this lady is not going to die. Her daughter was there, looking at her watch and trying to decide whether she should take the afternoon out of work. When I told them that her mother would have to be admitted to the ICU they looked at me like I was crazy and I thought: maybe I'm overreacting. It's my first week on call for the group. Maybe there's some other way to handle this that I would know, if I were more experienced. The ICU consultants will probably laugh at me. When I sat them down and said look, I need to know what you'd want if

you were really sick and needed a breathing tube, they exchanged glances that said, This one is nuts. Listen to her going on about ventilators and CPR. "I don't know," she said impatiently, flipping her hand at me. "Let's wait and see what happens." And I said no, if she got sick later she might be too sick to talk to me, and I needed to know what she would want. (All the while thinking, she's going to go back to my partner and say, well, the nurses were nice at the hospital, but boy, that new doctor. All gloom and doom. Can't you get rid of her?) So she sighed and said she'd lived her life, she didn't want the tube, or the CPR, none of that. And two hours later when I was back in the office tearing through the colds and the flus, the ICU resident called me. "Your lady's pressure is fifty," he said. "And she's oozing from all her IV sites," DIC. I hung up the phone, did two throat cultures, threw my bag in the car and went back to the hospital.

In all my deaths as a resident - all the codes, the 2:00 a.m. pronouncements of other people's patients, the people I extubated to let them die, I have never had one so wide awake. My partner's patient is sitting propped up in bed, her face white, her eyes wide and alert like dark beacons across the room, I cannot imagine what I will find to say to this woman, who looks keenly at my face for signs that she is doing badly. I sit down on her bed and take her hand, as cold and white as porcelain. My partner is at a conference and I am acutely aware that I am not him, that she would prefer him, that she is going to die with a stranger. I tell her what she knows: that her blood pressure has fallen despite our best efforts, that she's developed a very serious clotting problem, that we'll continue to help her as best we can through the night, but there probably won't be much we can do. I don't say the words "and then you'll die," but they hang in the room palpable as a shroud. "Okay," she says, looking at me like she's waiting for more. But there is no more. I pull a chair up next to her bed and tell her I will stay here with her until we can find her daughter, and she should let me know if she has any pain. We settle in to wait. The room is very quiet. Her humidified oxygen bubbles gently in the background, and at one point she asks if it is raining. I dim the lights. Periodically the blood pressure cuff inflates with an efficient whir. After a while I take it off and I take the O₂ sat monitor off too. She watches me do all these things but doesn't say anything. I consider asking her about her family, about what kind of work she did before she retired, about her home. I dismiss all these things as either banal or cruel, and I am left with no topics. She looks at me and I look at her. At one point she says, "Well, I guess you were right about me." It takes her a lot of breath to say this, and I realize she has gotten worse in the past hour or so. "Believe me," I say, "I'd rather have been wrong." I tell her that my partner, at a conference this week, would have wanted to be here. Her icy finger moves a little in my hand. "You're nice too," she says, her voice weak, but her gaze undimmed.

The night wears on. I have had no dinner, and I want to be here, I think it's important, but a large part of me wants to go home, eat something, and go to bed. There is no way I can say this to this woman, and so I continue to sit. I begin to feel lightheaded with hunger, my hand in hers is getting progressively colder. My mind begins to drift and I say almost auto-

matically, "There you go...breathe in and out...I'm still here..." And I realize something true about my life, about maybe everyone's: that it's always easier to talk to someone who's not listening, to want things you can't have, to say what you feel to someone who is unconscious, or not there. I think that I say soothing things at people's deathbeds mostly to comfort myself; I doubt they can really hear me. But here I am with this woman who is wide awake, and I'm saying them anyway, and she is looking comforted, and I think maybe this is the way it really should be, maybe I should worry less about sounding silly and unprofessional and not having the answers and not being my partner, and just be me. Let the true words come out and show themselves when people are awake, as well as when they are sleeping.

Her daughter comes at ten. I tell her how things are going, encourage her to take my chair. My patient is still awake, but looking very tired. "I'm going to let you two spend some time together," I say, my polite way of excusing myself usually, but then

I decide to tell the truth. "I need to get home," I say. "I'm sorry to have to go. Do you two have any

questions for me, or anything I can help you with?" Instead of being angry that I'm leaving, they both say they understand. Of course I should go; I've stayed long enough. They will be fine. "I'll be here in the morning," I tell my patient. We both know she will not be. She holds my hand, takes a few breaths to prepare for what she has to say. "This is a good doctor," she tells the daughter.

In the car on the way home, the full moon streaming down on the highway, I think about my first weeks of practice: how I constantly worry that people will know I'm new, how I try to sound professional, like I know what I'm doing, like I can help them, and how tonight, when I couldn't do a thing to help and didn't know what to say and sounded just like me, just me, was the first time one of my new patients told me I was a good doctor. I am very tired, and I think that by morning I will have forgotten this, and I try to remember.

Shortly after I fall asleep, the phone rings: the ICU resident, whose Middle Eastern accent grows more pronounced at night. "Your patient has died," he says. "Don't worry, everything is done." He means the paperwork, the death certificate, but when I roll over in bed to fall back to sleep I think he means everything, the total of our work with her, the whole experience, everything is done, and I know he is right in a way, and wrong in a way, because I can still remember, even half-asleep, the things I feared I would forget.

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A Day with Dr. Malaprop (or) On Burning Your Bridges at Both Ends

Stephen Davis, MD, and Tina Kenyon, ACSW

Authors' note: Dr. Malaprop is, of course, a fictional character. We have created his day from selections of the numerous malapropisms that we have been exposed to.

My favorite cardiologist called about Mr. O'Brien, whom I had referred back for recurrent chest pain after heart surgery. His evaluation suggested that his arterial bypass surgery had been unsuccessful. "Ah", I replied, "A stuffed CABG". Mr. O'Brien had already informed me that he had known from his first catheterization that he did not have congenial heart disease.

My next patient was an 85 year old with terminal metastatic cancer. Her family had taken exquisitely good care of her and her pain control had been amazingly good up until now. She was clearly upset. When I asked her what was bothering her today, she said that her family was feeling that she would benefit from more nursing care at home, and they had decided to put her in the hostage program. I had previously discussed end of life issues with her. I had asked if she had a living will. She had replied, "No, but I have a will to live."

My next patient was a middle-aged man. When I asked why he had come to the office, he answered, "I need a fiscal." In taking his history, I learned that he had had a fairly complicated appendectomy when he was a child. "Have a scar?", I asked. "No, thanks, I don't smoke", he responded.

I spent lunch-hour with a fifth-grade sex-education class at the local school. One of the students wanted to know why they call it "public hair if it is in the private parts." One boy wanted to know what the Army had to do with it: why were the privates and the generals in the same place? Another boy said that he had recently been kicked in his technicals.

Before I left the school I had a brief discussion with the school nurse about one of the older students who we were concerned had developed anorexia. We talked about how hard it is to get an accurate history from some teenagers. "Those girls who have an eating disorder will never give you the straight skinny on what they're

doing. One girl told me that it was her natural habitat to be thin."

"Yes, I'd like to be a flower on the wall when you have that discussion."

On my way out the school door, I met the mother of one of my kindergarten-aged patients. She said that she had been called to a meeting with the principal. "My son is having trouble relating because he is artistic." She added that in spite of his problem he should be streamlined to get the most out of school both educationally and socially.

On my way back to the car I decided to watch a little of football practice. I find high school sports quite amusing. The coach had asked the members of the team to pair up in threes, and they had had trouble accommodating to his wishes. He told me that until he realized what he had said, he was getting so upset with the boys that he was afraid that he would blow a gas cap. I told him that it now was just water over the bridge.

I asked the coach why his first string quarterback was not practicing. He told me that he had sustained a roto-rooter cuff tear last season and now he seemed to have a laxative in his shoulder.

As I got back in my car, I noticed that I was a little late in getting back to the office, so I stepped a little harder on the exhilarater to speed me along.

When I was back at the office, the Smiths came in for a discussion. They were reserved at first, but once the conversation began it became clear why. They had decided that Mr. Smith should get the shot to keep him from having any more children: the vaccinetomy. We discussed other components of their sexuality. "Impotence, you know, is no big thing," I said. "We'll jump off that bridge when we get to it," Mr. Smith replied.

One of my favorite patients was next, a teenager in for a pre-college physical. She had been to France on a school trip for spring break and had had a wonderful time. She wanted me to know that they had traveled to Normandy and had seen the home of the French heroine, St. Joan Aardvark. While she had been in Marseilles, she had had an allergic reac-

tion to something, but she recovered quickly since they had given her "Anthrax" for it. Now, she admitted, that was just water under the dam.

The nurse broke in to tell me about an urgent phone call. She had sent one of our first trimester prenatal patients to the hospital. She was having severe left-lower quadrant pain, and her husband was concerned that she might have an atomic pregnancy.

In primary care often one needs to balance medical treatment with complementary therapies that our patients may be using. My next patient was a middle-aged librarian who had fairly bad eczema and who was also concerned about her family history of senility. When I asked what other treatments she had been using, she replied that she really limited herself to herbal medicines. Lately, she said, she had been using ginkgo extract for her memory and alopecia for the skin dryness.

My next patient had ostensibly come in to have a tiny sebaceous cyst on his neck checked. It seemed very benign, even insignificant to me, and I noted to myself that this seemed unlike his usual denial about more severe medical problems. As he was leaving, he said, "Oh by the way, Doc, would I be able to get a prescription for that new medicine, Niagara?" I sat him back down, and we had a discussion about his sexual functioning. It seemed as though a brief trial of Viagra would be reasonable. I was concerned about whether his wife was involved in this decision. He assured me that they had discussed it thoroughly, and that he had no other involvements: "I'm not into that extra-terrestrial stuff," he declared emphatically.

A 8-year old boy was next. He was not known to have asthma, but he had been having an unproductive cough lately especially after playing soccer. He also had become a little short of breath from time to time. He seemed especially upset by these symptoms. I tried to console him, and asked if anything was bothering him. He was reluctant to admit it, but finally he said that his mother said that she thought he had a weasel in his chest.

The next patient was a young man with arm pain. He reported that he had caught his arm below the elbow in a car door last week, and ever since he had been having pain in his forceps muscle. He wondered if he could have a subscription for pain meds, and I began to wonder if this were a case of drug-seeking behavior. My suspicions were intensified when he told me that his wife was a barbiturate liar.

A middle-aged auto mechanic with diabetes was next. He was in for a follow-up visit from a skin abscess that I had worked on last week. When I walked in the room, he asked, "How did that sculpture of the sis on my back turn out?"

My next patient was a woman who also had been followed by our local pulmonologist for sarcoidosis. We both had been seeing her fairly regularly after her initial treatment. She reported that she had recently been to see her lung doctor, and she had good news: Her sarcoidosis was lying doormat.

A young woman was the next patient. Clearly embarrassed, she reported that she had a virginal itch that had been bothering her for some time. While I was fumbling for my follow-up question, she reported that she had been using Monastery 7 cream for it that had really not helped very much.

Later in the day I was returning phone calls to patients. Mr. Johnson wanted to let me know that his wife had self-referred to a surgeon. "He had to cut a pollock out of her," he said.

That evening it was my turn to see patients with acute problems and those who preferred evening appointments. While I certainly would have liked to have the evening off, I really did not mind taking my turn being the back-up pin cushion for the office.

The first evening patient was a college student who had a fever and sore throat and thought that he had a strep throat. After doing his rapid-strep test, I had to admit to him that he had pinned the nail on the head. "You're sharp as a whistle," I complimented.

Any excuse in a storm.

We would like to thank the audience at our Brown University 1998 commencement forum, "Medical Malapropisms As Diagnostic Clues", and other friends and colleagues—including Frank Schaberg, Esther Entin, Art Frazzano, Peter Mandelson, Bob Elliott, Donya Powers, and the ever-vigilant Kathy Papineau—for contributing many of the above malapropisms.

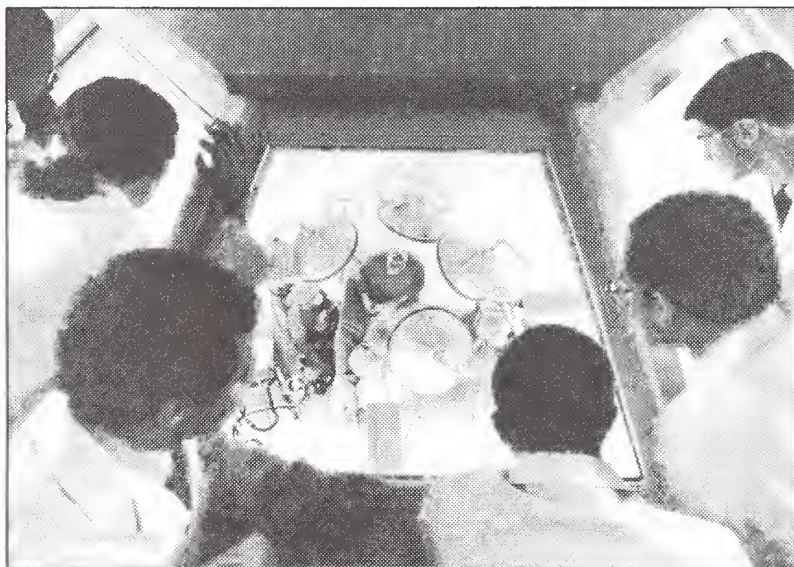
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Some Thoughts on the Treatment of Psychiatric Disorders in the Primary Care Setting

Sarah Aronson, MD

In the park-like atmosphere of the Butler Hospital as a medical student, I was drawn to the specialty of psychiatry by the interest and compassion for patients I sensed there among my supervisors, the nurses, and other mental health professionals. Psychiatry is a specialty distinguished by its focus on the patients' priorities and personal experience. I completed my residency, and though I enjoyed those aspects, it was discomfiting that there are few concrete answers to be found in psychiatry, or so it seemed to me. By the end of my residency, it was clear to me that I missed the broader hands-on practice of medicine. I decided to re-enter primary care.

Family medicine was a natural choice, as it allowed me both a wide range of clinical experience as well as an opportunity to integrate my psychiatry training into my patient care. Over several years of practice, and now in a position of teaching family medicine residents, I have given thought as to how a primary care physician (PCP) can best assist patients who struggle with mental illnesses. In my experience, many patients arrive to their office visits with an underlying psychiatric diagnosis, one that often is related to their current complaints. This presents an opportunity to improve the health and well-being of our patients. Unfortunately, statistics suggest that patients with mental illnesses often do not receive adequate evaluation or treatment for these disorders.

What are the obstacles to effective treatment of these patients in the primary care setting? And what can be done, within the framework of the average busy office practice, to improve the family doctors' interventions in these areas? A few studies have addressed this question, and there appear to be several factors.¹ These can be summarized into four areas: first,

awareness of the prevalence of mental illness; second, accurate diagnosis; third, collaboration with mental health consultants; and fourth, effective use of psychiatric medication.

Patients with common psychiatric problems such as depression, anxiety, substance abuse, and eating disorders often present with somatic complaints. A key step for the family doctor, in interviewing any patient, is to keep the relevant differential diagnoses in mind. She must then employ her skills and knowledge of symptom patterns to assess the patients' difficulties. While the PCP may worry that a review of common psychiatric symptoms will consume an inordinate amount of time, this evaluation can be done in the context of a brief office visit, and is a necessary part of a thorough clinical assessment. There are references available to the primary care practitioner which can guide the preliminary psychiatric review of systems, to allow a working initial diagnosis.^{2,3,4}

In my experience, a family physician may hesitate to conduct a psychiatric assessment because of a concern that she may be called upon to act as a psychotherapist. She is correct to feel unprepared for that role, both in terms of available time and training. While supportive counseling and education are central to the primary care of these patients, it is not necessary or appropriate to take the role of the patients' therapist. I work closely with clinical psychologists. Our collaboration over the years has deepened my understanding of the practice of psychotherapy, and the im-

Abbreviations Used:

OCD	obsessive-compulsive disorder
PCP	primary care physician

portance of delegating that aspect of a patient's care to a provider who makes that his or her specialty.

This brings us to the role of the mental health consultant. By the nature of our position in health care, PCPs know how to make use of consultants and how to maintain communication with them. This ability sometimes is lost when a psychiatric diagnosis is the central issue. As with consultants for any other medical or surgical problem, a mental health specialist can be involved at several stages in the care of patients with mental illness. A psychiatrist can be consulted to suggest medical management. Either a psychiatrist or psychologist can assume primary responsibility for the psychiatric care of these patients; this is often the best strategy when a patient is unstable, requires full or partial hospitalization, or has more complex diagnoses or treatment needs with which the family doctor is not familiar. Commonly, however, a collaborative approach will be effective.

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Rhode Island does not have a procedure for certification of specialization by lawyers.

Consider a situation in which you are interviewing a patient who complains of fatigue and palpitations. As you talk with him further, he reports that he is experiencing episodes of intense anxiety in certain circumstances, and is chronically late for work because of difficulty getting out of the house in the morning. You believe he suffers from an anxiety disorder but you are unsure of the specific diagnosis. Use of one of the references mentioned above may help you develop an initial assessment. The differentiation between anxiety syndromes such as phobia, panic disorder, or obsessive-compulsive disorder (OCD), however, requires a clinical familiarity with the range of possible diagnoses. There are evidence-based treatment approaches for each of these conditions, and accurate assessment is important. This is an appropriate time to consult a psychologist or psychiatrist and ask for a diagnostic evaluation, to develop treatment and referral recommendations.

In another circumstance, you may be prescribing psychotropic medication for a patient who is in psychotherapy with a mental health provider. As with any other clinical situation in which you are co-managing a patient's care with another specialist, it is important to maintain regular communication regarding the patient's clinical progress, and use that information to adjust your interventions appropriately. Unless the patient is clinically recovered and in a maintenance phase, it is important to evaluate the efficacy of your medical management at frequent intervals.



There have been many cases in which a consulting psychologist has brought my attention to a patient who needs an increase or re-evaluation of medication, or to one whose persistent depression has been missed behind the somatization which has occupied the patient's medical visits. In another instance, I have seen a patient treated with appetite suppressants, who, upon having a psychological evaluation, was found to have depression and binge-eating disorder.

Another setting in which collaboration is critically important is in the management of patients with eating disorders. The mainstay of treatment will be in the psychotherapy. Accurate communication with the therapist will facilitate the physicians' task of monitoring the patients' physical health, and will guide appropriate medical and therapeutic interventions. Many psychiatric disorders can be treated with counseling alone. It is important to be aware of this and use your relationship with a consulting therapist to know when that may be an appropriate recommendation.

Inadequate use of psychotropic medication can contribute to psychiatric treatment failures in the primary care setting. Family physicians have an opportunity to provide pharmacologic treatments for many of their patients with psychiatric disorders, and to enhance compliance with education and supportive counseling. With the advent of newer and safer antidepressants, more family doctors are willing to prescribe, but studies suggest they often do so without a clear understanding of dosing strategies, side effects, or the length of time needed to reach an adequate trial of medication.¹ The PCP should know what conditions can be treated with antidepressants, such as affective disorders, panic disorder, OCD, or bulimia, and be aware of the differing average doses often required for treatment of these conditions. Physicians more experienced with psychiatric diagnosis and pharmacotherapy can also become familiar with augmenting strategies used to treat patients who do not respond to initial trials of medications.⁵

The psychiatric disorders mentioned here are common, treatable, and create significant suffering and disability. More often than not, these patients will present for treatment initially in the family doctors' offices. My experience suggests that the primary care model of careful diagnosis, patient support and education, treatment, and guidance to appropriate referrals or consultation, can be effectively applied to these psychiatric problems without an expectation that the PCP become a psychotherapist. As with any other group of disorders, we should use this opportunity to treat what we can, to educate these individuals about their diagnoses and treatment, and to help them to make use of the psychological care that they need.

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Obstetrics in Family Practice

Richard Long, MD

The role of the family physician in delivering obstetrical care has long been controversial. Dr. Edward P. Davis, professor of obstetrics at several Philadelphia medical schools, in 1894 scolded general practitioners' performance of obstetrical care, citing their erroneous belief that "the condition of pregnancy... [is] naturally normal" and that "labor is a natural process".¹ At the turn of the 19th century, physicians argued for a more analytic and scientific approach to medical care with less empiric or anecdotal practice, an argument not entirely unlike the argument for evidence-based medicine today. While country physicians were often scorned for their lack of scientific application, even in 1894 generalist physicians recognized the unique demands that obstetrical practice placed on them. "If a country doctor should be a specialist in one branch of the science of medicine more than any other, it should be in that of obstetrics."²

The debate intensifies today as certain patient populations find it increasingly difficult to access obstetrical care. With maternity care being delivered by a variety of health care providers, including obstetricians, certified nurse-midwives and nurse practitioners, what role do family doctors have in assuring the provision of high quality, consistent care to pregnant women and their children?

BACKGROUND

Every year in the United States nearly four million babies are born. The vast majority of these deliveries are performed in metropolitan hospitals by obstetrician-gynecologists; however, an estimated 2-4% of births are delivered by certified nurse-midwives, and approximately 500,000 - 600,000 births each year are attended by family physicians.

Until recently the number of family physicians providing obstetrical care

had been declining. Forty-six percent of family physicians in 1978,³ and only 24% of U.S. family physicians in 1992 included obstetrics in their practices.⁴ This downward trend appears to be reversing. According to the most recent American Academy of Family Physicians (AAFP) survey, 30.5% of members in 1994 included obstetrics as part of their practice.⁵ An estimated 16,500 family physicians and general practitioners supply obstetrical care in this country and provide a substantial portion of the pregnancy care for women, including approximately 20% of prenatal care.⁶ The typical family physician averages 40 deliveries per year.⁷

VULNERABLE POPULATIONS

A major health problem in the United States is the maldistribution of maternity caregivers. With inadequate access and availability of care affecting vulnerable populations in both rural and inner-city urban communities, these under-served communities experience disproportionately high rates of infant and maternal mortality as well as other adverse health outcomes.

Twenty-five percent of Americans reside in rural areas where obstetrician-gynecologists make up less than 1% of the physician providers.⁸ The same declining trend of family physicians performing maternity care that has affected our nation disproportionately affects rural Americans where family physicians represent two-thirds of the obstetrics providers.⁹ The closing of obstetrical units and community hospitals across the United States further magnifies the disparity of services available.

Urban areas, too, experience real barriers to access and availability of maternity care. These barriers may not be directly related to geographic isolation, but rather from financial, language and cultural barriers. Maldistribution of physicians persists

Abbreviations Used:

AAFP	American Academy of Family Practice
ACOG	American College of Obstetricians and Gynecologists
STFM	Society of Teachers of Family Medicine

not only in rural areas, but also in inner-city urban communities where the metropolitan physician glut fails to extend.

NEW ENGLAND AND RHODE ISLAND

Family physicians in New England play a significant role in delivering care to pregnant women and their families. Nearly 30% of New England family physicians incorporate obstetrics into their practices,⁵ and these doctors are not limited only to the rural expanses of Maine, Vermont and New Hampshire. Fully 23.4% of urban family physician practices in New England include the practice of obstetrics.⁵

Though Rhode Island cannot claim vast, geographically isolated rural areas, we are home to distinct, vulnerable and economically disadvantaged populations, who confront multiple barriers in accessing care. By AAFP survey, more than one out of five family physicians in our home state are maternity caregivers.⁴ In Rhode Island, family physicians are privileged and provide an entire spectrum of maternity care from prenatal care and routine vaginal delivery, to complicated, high-risk care, including performance of cesarean section.

Although most of Rhode Island's obstetrics-providing hospitals have credentialing and privileging policies for family physicians, Memorial Hospital of Rhode Island is the only hospital in our state where the cooperative practice of obstetrics by family physicians is active and flourishing in collaboration with obstetricians, certified

nurse midwives and other health care workers. Memorial Hospital is a Brown University-affiliated hospital and is home to Brown University's Department of Family Medicine and the major clinical training site for the department's Family Practice Residency training program.

FAMILY PRACTICE TRAINING AND PRIVILEGING

Obstetrical training is an essential component of Family Practice. A joint task force of the American Academy of Family Physicians and the American College of Obstetricians and Gynecologists (ACOG) recently developed educational guidelines to assure that graduates of family practice residency programs are "well-prepared to provide quality medical care in the areas of maternity care, labor and delivery, and the female reproductive system".¹⁰ The guidelines outline a minimum requirement in ob-gyn education that emphasizes both ambulatory and hospital care. Suggesting that family physicians and obstetricians collaborate in the design, implementation, and evaluation of family practice residents' obstetrical training, the guidelines further outline recommended knowledge, core skills and advanced skills for residents. These fundamental knowledge, skills and judgment are a required base in every family physician's practice, even if not directly translated into obstetrical care.

Obstetrical management is an integral component of any family physician's practice. Even in practices where prenatal or maternity care is not routinely delivered, a level of expertise in obstetrics is necessary, because primary care patients may present with myriad pregnancy-related issues. A

family doctor may be called upon to manage, for example, diagnosis of pregnancy, preconception counseling, family planning, infertility, miscarriage, diagnosis of ectopic pregnancy, immunization requirements of the gravida, information regarding safety and use of over-the-counter medications, management of concomitant illness in pregnancy, breast feeding support, and recommendations for preventive health care.

*Here in Rhode Island,
family physicians. . .
provide an entire
spectrum of maternity
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performance of cesarean
section.*



While successful completion of obstetrics and gynecology training is essential for graduation from family practice residency programs, it does not assure a resident of attaining hospital privileging or credentialing. Depending on their experience and level of competence developed in residency, some residents will seek to attain hospital privileges directly, while others will elect to obtain additional training in obstetrics. Family practice residency graduates may also pursue post-residency fellowship training in obstetrics.

Assignment of hospital privileges is determined locally and is

based on training, experience and competence. In 1998 a task force of the AAFP and ACOG developed a joint statement on maternity care practice and hospital privileges, which acknowledges the important

public health impact of obstetrical care as performed by obstetricians, nurse midwives and family physicians in the United States.¹¹ The intent of this joint document is to promote the highest standards of care through the fostering of collegial relationships between specialties.

SHOULD FAMILY PHYSICIANS PRACTICE OBSTETRICS?

While misconceptions about quality of care, scope of practice, fear of liability, disruption of lifestyle and costs of malpractice insurance may discourage a family physician from including obstetrics in practice, the rewards of practicing obstetrics often outweigh the deterrents. Family Medicine offers continuity of care for both mother and her baby, affords the clinician a youthful practice profile, brings in more revenue, and offers the practitioner a sense of accomplishment and satisfaction.

Patients, too, reap rewards. Without the arbitrary dissection of pregnancy care from infant and child care the family physician can attend the woman and infant and, for that matter, the entire family throughout all stages of life. Family physicians with a unique, family-centered approach, expertise in providing continuity of care, and community sensitivity offer more comprehensive care for women in childbirth.

Extensive evidence and literature reviews have supported the high quality of obstetrical care provided by family physicians. Citing 26 individual studies between 1975-93, Larimore and Reynolds¹² summarized:

"Studies have revealed that low-risk women cared for by family physicians have equal or better outcomes than do similar women cared for by obstetricians, that cesarean section rates are highest where obstetricians give primary care, that family physicians are more likely to provide non-interventional maternity care, and that family physicians and midwives have similar outstanding outcomes. Furthermore, family physicians provide primary care at a lower cost than do other physicians." As Walter Larimore, MD, a Florida family physician who prac-



tices obstetrics, concludes, "There is no scientifically supportable reason for excluding family physicians from maternity care in any setting..."¹²

Somewhat more difficult to address are the political and economic obstacles which confront many family physicians across the country pursuing hospital obstetrical privileges. Obstetrical privileging for family physicians is frequently denied under the tenet of insuring quality of patient care, when specialty territoriality, departmental control and assurance of financial monopoly seem often more suspect and legitimate concerns. These arguments have taken on the analogy of battle¹³ and been referred to as "turf wars."^{14,15}

"Can C-sections be done by FPs, or only by Ob/Gyns? Can Ob-Gyns be primary care physicians, or only FPs?"¹⁶ Quite frankly, any medical specialty whose duties overlap significantly with another will encounter friction and the need to delineate territory. These turf wars have long placed Family Practice in an uncomfortable position, a metaphorical Israel of the Medical East, carving out its existence from the perceived territory of others while simultaneously defending its borders against those who would encroach, restrict or take possession of that which was dutifully achieved. This metaphor begs the naïve and timeless question, "Why can't we all just get along?"

William Rodney, MD, in his testimonial on behalf of obstetrical privileging in family practice and addressing unnecessary denial and obstruction of hospital privileges for family physicians responds, "For the public's health, this means that many women have had their lives needlessly endangered by poor access to obstetrical services, when family physicians could have provided those services if they had appropriate hospital privileges. For the health of the public, therefore, it is absolutely critical that qualified family physicians receive obstetrical hospital privileges (including cesarean section) when they can demonstrate the necessary training, experience, and/or proven ability."¹⁷

There exists a belief, pervasive among many obstetricians, that family physicians cannot possibly be competent to manage childbirth, routine or otherwise.¹⁸ "After all, there's no question that they don't meet the same standards for training and education in OBG that we do," states Larry Griffin, MD, Director of Program Services at ACOG.¹⁴ This attitude propagates unsubstantiated biases that are virulent and infectious, replicating into new generations of obstetricians. As is the case with most prejudices, this attitude can be insidiously effective on the parties to which it is directed, undermining self esteem, slowly and progressively eroding self confidence, and ultimately creating an environment of learned helplessness and dependence. Many family physicians, constantly confronted with the assertion by their peers that they are "not good enough," become their own worst enemies. With lingering self doubt we risk losing that which is essential in the delivery room and vital for developing the trust of our patients. We risk losing confidence in our own abilities.

SUPPORT OF FAMILY PHYSICIANS DELIVERING BABIES

Luckily, family physicians are resuming the call to include perinatal care back into our practices. Forty to 50% of Brown University/Memorial Hospital of Rhode Island graduating Family Medicine residents each year include obstetrics care into their practices. Our Maternal and Child Health fellowship, co-administered through our Department of Family Medicine and the Blackstone Valley Community Health Care, Inc. community health centers is in its ninth year of training selected family physicians with advanced obstetrical, neonatal and community health skills. Fellowship graduates serve in under-served communities and in academic Family Medicine departments throughout New England, across the country and around the world.

Support for family doctors who deliver babies is proliferating. Networks of local family physicians who deliver maternity care support one another through shared call arrangements, continuing education opportunities and cooperative teaching programs. Nationally, hospital, county, state and regional medical associations offer activities to enhance the maternity caregiver's practice. The AAFP and the Society of Teachers of Family Medicine (STFM) sponsor maternity care conferences and educational opportunities to augment provider skills, publish obstetrics-related research, review standards of practice, encourage the development of clinical guidelines, and, through a national network of family physicians, support the entire spectrum of family medi-



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cine obstetrics practices including advocacy for privileging. With growing support from and collaboration with our nurse midwife and obstetrics colleagues, family doctors also take advantage of educational opportunities provided by other disciplines.

More important than any of these organized educational activities is the relationship we build with our obstetrics-providing colleagues. No single statement concerning this relationship is more revealing or central to our goal than that of Kruse, "If maternity care is to remain an important part of the specialty of family practice, the relationship between obstetricians and family physicians must be strengthened."¹⁸ Today, when the spirit of partisan politics sets the standard for conflict resolution, and the economics of health care forces alien competition into the doctor-patient relationship, those of us who have been entrusted to care for the health and well-being of our patients must work together.

"When the needs for a strong primary maternity care system are so great, it makes good sense for all maternity care practitioners to support one another, to rethink their philosophies and priorities, and most important of all, to put the needs of the pregnant woman and her family first."¹⁹

When we share with one another what we each do best, we improve the quality of our care, and patients reap the rewards of our mutual successes. Collaboration, as envisioned by the AAFP and ACOG Joint Task Force, should include the programs where we train our practitioners and extend into the practice of our specialties. Where seeds of mistrust or suspicion might germinate, cooperation among our disciplines can forestall biases. Rather than striving for all maternity

caregivers to become stereotypical and interchangeable, we might thrive collectively in our individual approaches, simultaneously appreciating and utilizing the valuable and unique contributions of our colleagues. As family physicians, as nurse midwives, as obstetricians, we gain through collaboration, cooperation and support than can be gained through divisiveness and conflict. Let us continue to put aside what separates us as different, and embrace what we share as common ideals.

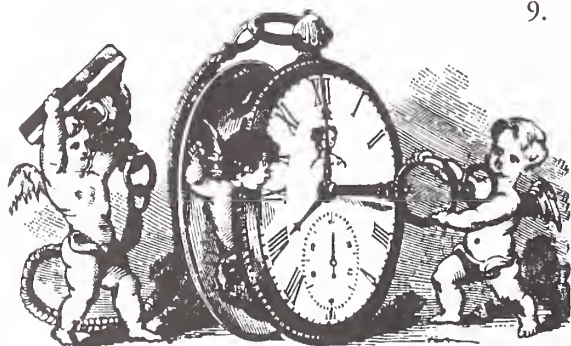
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A Tale of Costs and Markets: Predatory Pricing

Max Powell, Leslie Tucker, and Nisha Lodhavia

Earlier this year, the Governor's Advisory Council on Health was charged to explore the assertion that health care in Rhode Island is "less expensive" than health care in Massachusetts and Connecticut - an assertion consistent with reports of lower health insurance premiums in Rhode Island than in Massachusetts.

The reality, though, is that costs have been comparable - but premiums lower. In short, costs do not translate directly into premiums. In the commercial insurance market, the cost of health care can be captured in the per member per month medical expenses (PMPM expenses) reported by health plans. Health plans in both Massachusetts and Rhode Island have historically reported medical expense levels higher than those in Connecticut and the nation as a whole. In fact, Interstudy health plan survey data show that between 1997-1998, Rhode Island health plans' PMPM expenses exceeded by 6% those reported by eastern Massachusetts plans.

Nevertheless, insurance premiums are subject to the competitive pressures of the marketplace, and insurers have charged rates in Rhode Island well below those in Eastern Massachusetts. The following table shows the disjuncture between costs and premiums. At least for their commercial products, the health plans in Rhode Island have accepted premiums well below the level which their actu-

aries have determined are necessary to support the benefits delivered to members.

Health plan pricing tends to follow a cycle, with corporate focus toggling between increasing membership/market share, and increasing financial reserves/net worth. Generally to attract market share, health plans try to keep premiums low. Not surprisingly, the health plan with the greatest gain in market share probably is offering the most attractive prices. Yet if/when a health plan reduces prices too low - where the revenue will not cover the costs of medical care for enrollees - then the plan must either raise premiums or tap into its financial reserves to pay benefits. Individual insurers will make that decision based on their own competitive objectives (e.g., buying market share) and financial realities (e.g., declining net worth). The resulting S-shaped curve that describes both premium levels and net worth per member over time is primarily the result of this pricing cycle.

Health plans in Rhode Island have

been collecting premiums that are insufficient to support their operating costs. The market conditions driving that phenomenon appear to have, at least temporarily, produced commercial health insurance rates in Rhode Island that are more attractive than those in adjoining markets. This potential economic advantage, however, cannot be sustained as the competitors remaining in the market are forced to raise premiums, to assure the continuing financial viability of their plans.

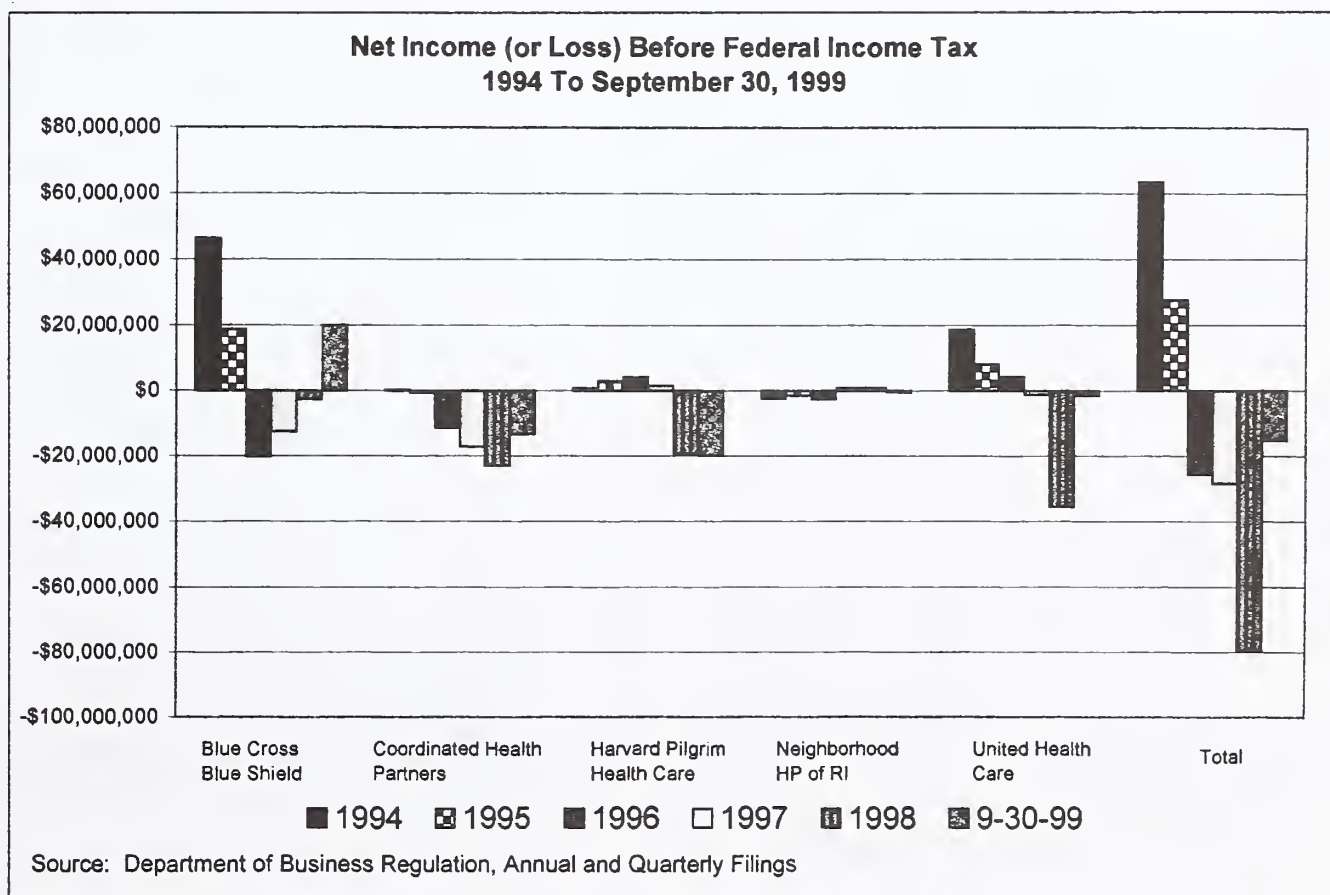
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Living Healthy in the New Millennium Prevention Campaign

Edward Westrick, MD, MS

Rhode Island Quality Partners (RIQP) is proud to continue as the HCFA-contracted Peer Review Organization in Rhode Island. In November we started our new scope of work, improving health care for Medicare beneficiaries in our state. Over the next three years we will continue to work with hospitals, health plans, and our other partners on quality improvement projects and we look forward to a closer working relationship with practicing physicians. We anticipate additional projects in long term care and home care settings. Our beneficiary outreach program will focus on the six national priority topics: myocardial infarction, heart failure, pneumonia, stroke, diabetes mellitus, and breast cancer. We have included an example of a beneficiary-targeted communication.

The "Living Healthy in the New Millennium" campaign began with the publication of the attached checklist in the *Providence Journal* in late November. In addition, the prevention checklist will be printed and distributed to senior sites throughout RI, including physician offices, senior centers, churches, and senior housing complexes. As you can see, your patients should be coming to you for sign off on the completion of these important preventive services. This is a good time to reinforce to your patients the value of these preventive behaviors. Remember that less than half of all Rhode Island seniors get a yearly flu shot, and the number of seniors who have had a pneumonia shot is even lower. In 1998, less than 25% of all women between the age of 65 and 74 took advantage of Medicare's mammography benefit. In Rhode Island more than 18,000 people age 65 and older have diabetes. Yet less than half of all people with diabetes have an annual dilated eye exam.

We look forward to working with you over the next few years to further improve health care for Medicare beneficiaries. There are many ways that you can participate. For example, in November we held a focus group of physicians and office staff to give us feedback on materials we are developing. We anticipate the need to convene additional focus groups over the next few years. We recognize the value of your time and plan to provide honoraria for par-

Abbreviations Used:

HCFA	Health Care Financing Administration
RIQP	Rhode Island Quality Partners

ticipants. As always, we remain open to suggestions and new ideas. Please feel free to contact me about any of RIQP's projects.

Edward Westrick, MD, MS, is the Chief Medical Officer of Rhode Island Quality Partners. He is a member of the clinical faculty of Brown University School of Medicine and the Active Medical Staff of Roger Williams Medical Center. He is currently a PhD candidate at the University of Rhode Island studying Pharmacoepidemiology and Pharmacoeconomics.

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The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.

For
Adults Age 65
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In The New Millennium!

Win
\$500!

Rhode Island Quality Partners (RIQP) has developed this convenient prevention checklist to help you take control of your health in the year 2000. When you have completed all of the preventive services that apply to you and have gotten your doctor's / nurse's signature for each service, please return this form to RIQP. For your effort and commitment to good health, you will receive a free gift and we will place your name in a drawing to win \$500! **Forms must be returned no later than December 31, 2000 to Rhode Island Quality Partners, 9 Hayes Street, Providence, RI 02908.**

For Everyone: ☒

- ☐ **Colorectal Cancer Screening** Date Received: _____
Physician / Nurse Signature: _____
- ☐ **Flu Shot** Date Received: _____
Physician / Nurse Signature: _____
- ☐ **Pneumonia Shot** Date Received: _____
Physician / Nurse Signature: _____

For People With Diabetes: ☒

- ☐ **Hemoglobin A1c Rate** Date Received: _____
Physician / Nurse Signature: _____
- ☐ **Lipid Profile Rate** Date Received: _____
Physician / Nurse Signature: _____
- ☐ **Dilated Eye Exam** Date Received: _____
Eye Care Professional Signature: _____

For Women: ☒

- ☐ **Screening Mammogram**
Date Received: _____
Physician Signature: _____
(or X-ray Technician)

Please Print:

Your Name: _____

Street Address: _____

City/Town: _____ **State:** RI

Zip: _____ **Telephone #:** _____

If you have questions regarding any of the preventive services listed on this checklist, please talk to your doctor or call toll-free RIQP's Medicare Beneficiary Helpline at **1-800-662-5028**. More information on Medicare coverage of preventive services is available on the Medicare Web site at: www.medicare.gov.



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☞ Rhode Island's Cardiac Services Registry ☞

Michael K. Dexter, MPA, and Jay S. Buechner, PhD

Cardiovascular diseases are increasingly likely to be diagnosed and treated with high-technology medical and surgical procedures. In order to monitor and evaluate the use of these procedures, the Rhode Island Cardiac Services Registry (CSR) was established under an agreement between the Rhode Island Department of Health and the five hospitals in the state offering these procedures (Kent County Memorial Hospital, Memorial Hospital of Rhode Island, Miriam Hospital, Rhode Island Hospital, and Roger Williams Medical Center). The CSR collected information on the provision of the following services to adults (ages 18 and older) from November 1994 through December 1997:

- 1) cardiac catheterization with angiography
- 2) percutaneous transluminal coronary angioplasty (PTCA)
- 3) open-heart surgical procedures (primarily coronary artery bypass grafts, or CABG)

This analysis presents a brief summary of utilization data for calendar years 1995 - 1997 reported in detail in the CSR's annual reports.^{1,2} The CSR has also analyzed and reported data on the outcomes of these procedures in a separate report.³

Methods

Hospital staff identified CSR-covered procedures from hospital procedure logs and abstracted data on each procedure

from patient medical records for processing by the CSR contractor, Clinical Trials & Surveys, Inc. (C-TASC). Items collected for each procedure included patient identifiers and demographic characteristics, risk factors for heart disease, patient's symptoms being treated, expected source of payment, procedural details and results, and patient outcomes. C-TASC linked procedures performed on the same patients during multiple hospital admissions and performed all data analysis from the linked data file.

Abbreviations Used:

C-TASC	Clinical Trials & Surveys, Inc.
CABG	coronary artery bypass graft
CSR	Cardiac Services Registry
PTCA	percutaneous transluminal coronary angioplasty

Results

During the three-year period 1995 - 1997, a total of 17,964 angiographies, 5,955 PTCAs, and 4,685 open-heart surgeries were performed in the five hospitals offering one or more of these services. Just under half of patients underwent diagnostic angiography only, and most of the remainder underwent diagnostic angiography followed either by PTCA or open-heart surgery. (Table 1)

Table 1. Types of Procedures Performed on Cardiac Patients, Rhode Island, 1995 - 1997

Type of Procedure*	1995		1996		1997		Total	
	N	(%)	N	(%)	N	(%)	N	(%)
Angiography Only	2606	(47)	2886	(47)	2817	(45)	8309	(46)
Angiography and PTCA	1340	(24)	1525	(25)	1650	(26)	4515	(25)
Angiography and Surgery	1066	(19)	1214	(20)	1224	(20)	3504	(20)
Angiography, PTCA and Surgery	75	(1)	97	(2)	100	(2)	272	(2)
PTCA Only	169	(3)	149	(2)	144	(2)	462	(3)
Surgery Only	247	(5)	295	(5)	333	(5)	875	(5)
PTCA and Surgery	5	(0)	3	(0)	4	(0)	12	(0)
Total Patients	5508	(100)	6169	(100)	6272	(100)	17949	(100)

*Patients may undergo more than one procedure of a type during the course of their treatment, e.g., repeat angiography.

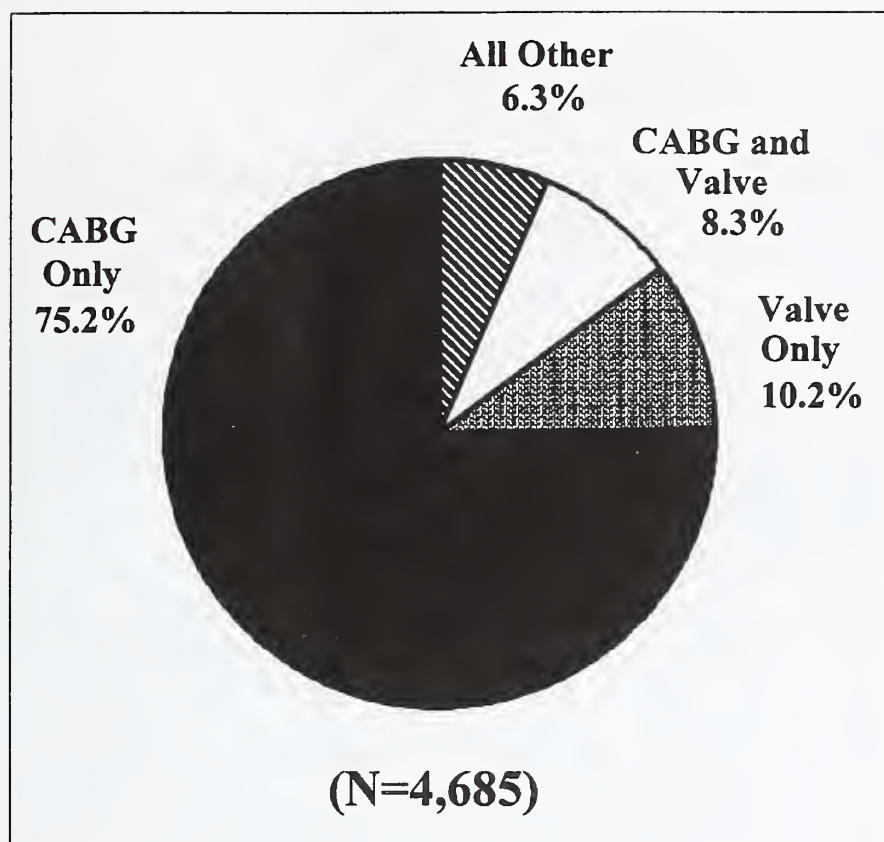


Figure 1. Open-Heart Surgeries by Type of Surgery, Rhode Island 1995-1997.

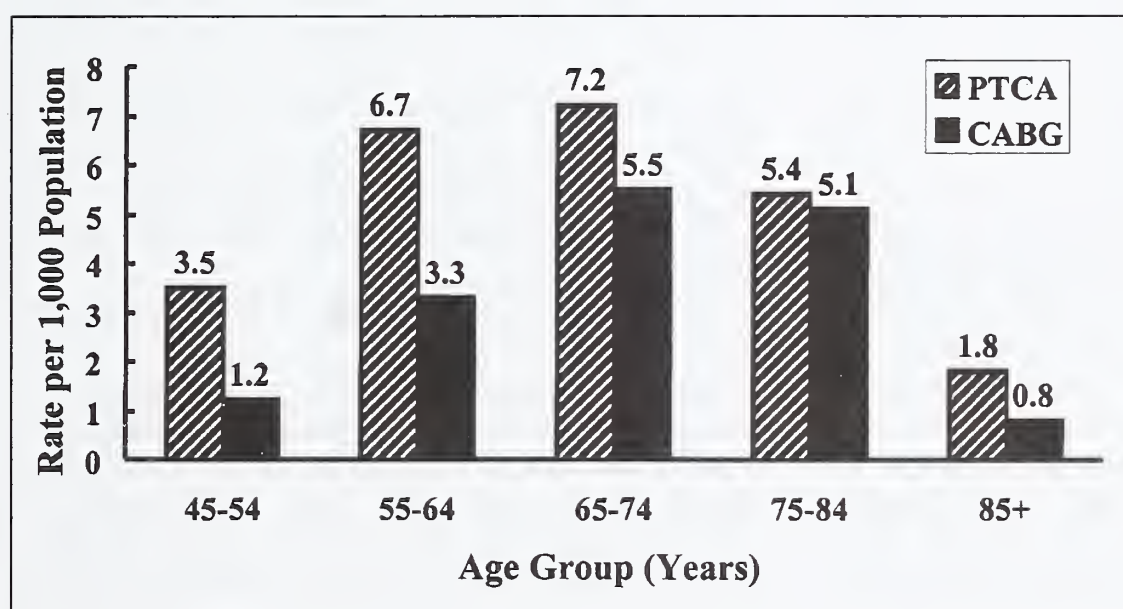


Figure 2. Percutaneous Transluminal Coronary Angioplasty (PTCA) and Coronary Artery Bypass Graft (CABG) Surgery Procedures per 1,000 Population, by Age Group, Rhode Island, 1995-1997.

Over the three-year period, both the numbers of procedures and the number of patients undergoing these procedures increased. The number of patients increased by 13.8% from 1995 to 1997, the number of angiographies by 15.4%, the number of PTCAs by 20.4%, and the number of open heart surgeries by 19.4%. The numbers of procedures performed increased more rapidly than the number of patients because the proportion of patients having more than one procedure increased.

Most of the open-heart surgeries performed were coronary artery bypass graft (CABG) surgeries, either performed alone or in combination with procedures to repair or replace heart valves. (Figure 1) Of the surgeries not involving CABG, the majority were heart valve procedures.

The two most common interventional procedures, PTCA and CABG, differed in their rates of performance

among patients of different ages. In all age groups examined, PTCA was more often performed than CABG, but among adults ages 44-64, PTCA was between two and three times more often performed than CABG. (Figure 2) Among persons ages 65-84, CABG was nearly as likely to be performed as PTCA. Overall, the majority of invasive cardiac services were provided to patients ages 65 years and older, including approximately half of all angiographies and PTCA's and two-thirds of all open-heart surgeries.

Discussion

Several states, including New York, Pennsylvania, and New Jersey, collect statewide data on open-heart surgery, and at least one state, New York, collects statewide data on PTCA. These data are used to measure and publish risk-adjusted mortality rates for each provider (hospital and physician) performing CABG and/or PTCA in those states.

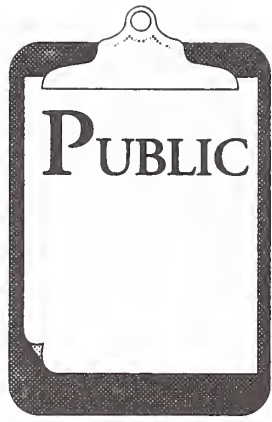
During 1994-1997, Rhode Island was the first state to collect statewide linked data on angiography, PTCA, and open-heart surgery. These data have been published in comprehensive annual utilization reports and in a report on statewide and hospital-specific outcomes of these procedures.¹⁻³ Currently, the Department of Health is working with hospitals, cardiologists, and cardiac surgeons to determine the future configuration of a cardiac services registry that will best serve the needs of the people of Rhode Island.

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Tobacco Control Report Card: Rhode Island, 1999

Donald K. Perry, MPA, and Dorothy Darcy, AS, CTR

As the decade draws to a close, the Rhode Island Department of Health and the Cancer Information System (Hospital Association of Rhode Island) have developed the following report card to evaluate progress toward a tobacco-free Rhode Island. The report card looks at trends in major smoking indicators during the 1990s and highlights those areas that require additional efforts. Grades of A and B indicate progress, C denotes little or no change, and D and F signal worsening trends. The report utilizes a variety of statewide data sources,^{1,2,3,4,5} including the Rhode Island Cancer Registry, the Behavioral Risk Factor Surveillance System, the Adolescent Substance Abuse Survey, and the Youth Risk Behavior Survey.

The data indicate that fewer Rhode Island men are dying from lung cancer. This outcome parallels the decreasing trend in overall cigarette smoking among adults, which commenced in the 1960s. Quitting or smoking cessation accounts for most of this reduction. Nonetheless, the decline in overall smoking statewide has decelerated in recent years, primarily due to an increase in tobacco use among young adults. The male smoking rate has actually stabilized during the past decade, which may begin to slow down the declining trends in lung cancer incidence and mortality experienced by men in recent years.

Unlike men, Rhode Island women have experienced higher lung cancer incidence and mortality rates since the early 1990s. This increase reflects the historical trend that women began to smoke in substantial numbers much later than did men. Therefore, women lagged years behind men in the development of lung cancer and other tobacco-related diseases. However, female smoking statewide has begun to decline, which should result in fewer cases of lung cancer and deaths in the future. Despite progress among both men and women, there remains much room for improvement. As role models and influential advisors, health care providers should enhance efforts to urge smokers to quit by offering periodic counseling and follow-up. Providers can also prescribe medications or refer patients to smoking-cessation programs or self-help products.

In contrast to cessation, smoking prevention is largely a youth issue, because tobacco use generally commences in

childhood. Concurrent with a

Abbreviations Used:

ETS	environmental tobacco smoke
-----	-----------------------------

period of massive tobacco industry advertising aimed at youth, there has been an alarming increase in smoking among Rhode Island high school students. By 1997, one out of three adolescents smoked cigarettes, whereas only one out of five smoked in 1993. Girls continue to smoke at a slightly higher rate than boys, but both groups have experienced similar increases in smoking overall. Health care providers, state leaders, local communities, youth organizations, schools, and parents should increase efforts to prevent our children from smoking through education, restricted access to tobacco, counter-advertising, and positive role modeling.

Rhode Island data largely mirror national data on tobacco use.

Another serious public health concern is exposure to environmental tobacco smoke (ETS), or secondhand smoke. Classified as a Group A carcinogen by the U.S. Environmental Protection Agency, ETS poses a severe health danger. Secondhand smoke is known to cause or exacerbate lung and throat cancer, emphysema, bronchitis, pneumonia, asthma, and other respiratory diseases. Rhode Island has had some success in eliminating ETS from public places,

Health Alert

The Rhode Island Department of Health strongly recommends to parents not to take children into restaurants that allow smoking. Tobacco smoke is hazardous to health. It is especially hazardous to the health of children. A list of smoke-free restaurants in Rhode Island may be obtained by visiting the Department's website:

<http://www.health.state.ri.us/disprev/assist/info.htm>

Patricia A. Nolan, MD, MPH
Director of Health

Table 1: Health Burden of Tobacco Smoking by Sex
1991-94 baseline vs. 1995-97 latest

Lung Cancer Incidence Rate (New Cases of Cancer per 100,000 Population, Age-Adjusted to the 1970 US Pop)	Base Rt. RI	Latest Rt RI	Progress Grade
Males	89.9	88.4	C
Females	46.6	51.5	D+
Lung Cancer Mortality Rate (Cases or Deaths per 100,000 Population, Age-Adjusted to the 1970 US Pop)	Base Rt. RI	Latest Rt RI	Progress Grade
Males	77.3	71.1	B
Females	34.0	39.4	D+

Table 2: Tobacco Smoking Cessation among ADULTS by Sex
1991-93 baseline vs. 1996-98 latest

Cigarette Smoking Rate (% of adults over age 18 smoking cigarettes)	Base % RI	Latest % RI	Progress Grade
All Adults (over age 18)	23.7	23.1	C+
Males	25.2	25.0	C
Females	22.4	21.5	B-

Table 3: Tobacco Smoking Prevention among YOUTH by Sex
1993 baseline vs. 1997 latest

Cigarette Smoking Rate (% of youths grades 9-12 smoking cigarettes)	Base % RI	Base % RI	Progress Grade
All Youth (grades 9-12)	21.5	33.8	F
Males	20.2	33.4	F
Females	22.8	34.3	F

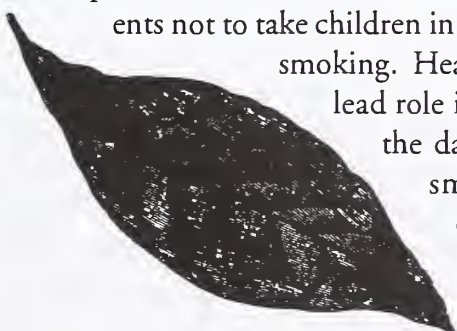
Table 4: Exposure to Environmental Tobacco Smoke in Worksites and Restaurants
1995 (Worksites), 1999 (Restaurants)

Type of Location	Latest % RI	Progress Grade
Worksites (highly restrictive of smoking or smoke-free)	85.0	B+
Restaurants (smoke-free)	9.5	C-

especially within the workplace. In 1995, 85% of the State's businesses had highly restrictive smoking policies or were smoke-free.

The status of secondhand smoke in restaurants is less encouraging. Although the number of smoke free restaurants increased from a handful in the early 1990s to approximately 500 statewide, nine out of ten restaurants still allow smoking. Children are especially at risk for the harmful respiratory effects of ETS, and within non-smoking families, children are more likely to be exposed to smoke in restaurants than anywhere else. For these reasons, the Department of Health has issued an alert advising parents not to take children into restaurants that allow smoking.

Health providers can take a lead role in reminding parents of the dangers that secondhand smoke presents to their children.



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Judicial Diagnosis

Improved Access for Patients or Health Care Fraud?

Hospital Provision of Office Space to Physicians

Lawrence W. Vernaglia, JD, MPH

Physician X, who has admitting privileges at Hospital A and sees inpatients there, leases hospital space from Hospital A, where he sees many of those same patients as outpatients. The arrangement is convenient. Is it illegal? It depends.

One common relationship, the provision of office space by hospitals to physicians, demonstrates how normal notions of business are unnaturally subjugated to the arcana of Medicare law. This essay discusses those rules and offers the proposition that they do not necessarily accomplish the public policy goals envisioned by the legislators.

In deciding to lease space from a hospital, a physician (or physician group) weighs numerous considerations, including access to patients, specialists, laboratory services, and hospital outpatient facilities, as well as the more mundane parking, physical plant, and infrastructure needs that any tenant must contemplate. Hospitals examine whether these physician-staffed locations should be operated instead by the hospital as a provider-based outpatient facility and premise, purchased outright as hospital-owned physician practices, or rented for profit to entirely different entities. However, at the core, hospitals, physicians, and patients benefit when physicians are located close to the hospital and its outpatient or satellite facilities.

Nevertheless, whenever health care providers have financial dealings, the relationship must be analyzed under the relevant federal and state laws governing health care fraud and abuse. In the case of physicians, these transactions must also be evaluated for compliance with the Stark II physician self-referral law.

STARK II

Section 1877 of the Social Security Act (the "SSA") prohibits a physician from referring patients to an entity with which s/he has a direct or indirect financial relationship (either through ownership or compensation) for the provision of certain "designated health services" covered by Medicare or Medicaid ("Stark II" or the "Stark Law"). The Stark Law creates a *per se* prohibition on physician referrals to such entities for designated health services unless certain exceptions are met. Although the Health Care Financing Administration (HCFA) has published final regulations to the so-called Stark I Law (which was similar to Stark II except that it applied only to clinical laboratory service referrals, not to all designated health services), it has not published final

rules under Stark II. HCFA has published a Proposed Rule under Stark II.¹ Providers are not required to follow the Proposed Rule, but advisors caution that the Proposed Rule demonstrates HCFA's current thinking on Stark II.

Regardless of the amount of rent paid, the transfer of the office space to the physician, and the payment of rent by the physician to the hospital, can constitute a direct or indirect compensation relationship – thus triggering the Stark Law.

If the Stark Law implicates the transaction, unless the financial relationship fits within an exception, the physician may make no reimbursed referrals for "designated health services." Hospitals commonly provide "designated health services" (clinical laboratory services; physical therapy; occupational therapy; radiology, including MRI, CT scans, and ultrasound; radiation therapy; DME; parenteral and enteral nutrients, prosthetics, orthotics, and prosthetic devices; inpatient and outpatient hospital services; and, occasionally, home health services and outpatient prescription drugs.²) In other words, unless a financial relationship meets an exception, a hospital may not be reimbursed for any of these services when referred by a physician with the financial relationship. Additionally, violators may be subject to civil penalties of up to \$15,000 per claim and \$100,000 for "circumvention schemes" designed to get around the statute, as well as exclusion from the Medicare and Medicaid programs.

The Stark Law has always included an exception for certain arrangements for rental of office space. In introducing his bill, California Congressman Fortney "Pete" Stark explained that "[b]y providing this exception, the bill accommodates legitimate concerns about patient convenience."³ This exception can be satisfied, however, only if the lease meets all of the following criteria:

- 1) the lease is set out in writing, signed by the parties, and specifies the premises covered;
- 2) the space leased does not exceed that which is "reasonable and necessary for the legitimate business purposes" of the lease and is used exclusively by the lessee, except that the lessee may make payments for the use of common areas if such payments do not exceed the lessee's *pro rata* share of expenses;

- 3) the lease has a term of at least 1 year;
- 4) the rent is set in advance, consistent with "fair market value," and not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; and
- 5) the lease would be commercially reasonable even if no referrals were made between the parties.⁴

The one-year lease rule prohibits most at-will tenancies by a physician where a hospital or hospital-related entity is the landlord. This requirement will also likely be interpreted by HCFA to preclude provisions for early termination without cause. Although termination without cause after the first year of the term is not clearly out of compliance at this time, after HCFA finalizes the Stark II regulations later this year they likely will be. Early termination for "good cause" should remain appropriate.⁵

The method of determining the rental payments is also critical, and departs from traditional landlord-tenant relationships. The rent must be for "fair market value" and may not exceed that which any other tenant would pay for the same space—even though a physician may value the location more in light of its proximity to the hospital. Fair market value appraisals from local realtors are reasonably reliable indicators of prevailing market rents, and should be received in writing. Unlike the relevant safe harbor to the anti-kickback laws, discussed below, rents may fluctuate based on a predetermined formula. Such formulae may take into account uncertain maintenance costs, insurance, taxes, or usage of the space. Rents based on percentages of profit or billings may not meet the exception and could also violate the anti-kickback laws or general prohibitions on fee splitting.

ANTI-KICKBACK LAWS

If the Stark Law does not apply or, if it does, an exception is met, then the next question is whether the transaction would be illegal under federal or state anti-kickback laws. Unlike the Stark Law, the federal anti-kickback statute and the Rhode Island Patient Protection Act are criminal laws. Consequently, it is more difficult to prove a violation. Also, a finding of guilt requires proof of criminal intent.

These statutes make it illegal to knowingly or willfully pay or receive any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind for referring patients or for arranging for, or recommending the ordering of, any services payable under a federal health care program.⁶ The Rhode Island Patient Protection Act prohibits the same activities but is an "all payor" statute, thus triggering penalties for violators who refer patients for services reimbursable by private payors.⁷ Violation of the anti-kickback laws can be punishable by substantial fines as well as

prison sentences, program exclusion, and professional license revocation.

Unlike the Stark Law, a relationship that appears to meet the criteria in the anti-kickback laws is not necessarily illegal. This is because a violation must include the requisite criminal intent. Likewise, if a "safe harbor" is not met, or is met only in part, the transaction is not necessarily illegal; whereas a Stark Law exception *must* be met for billing to be permissible. In evaluating office leases, the argument could be made that excessive rent charged to the physician is a kickback from the physician to the hospital to induce referrals to the physician, and that below-market rent (or no rent at all) is remuneration from the hospital to induce the physician to refer patients to the hospital.

Congress and the Office of the Inspector General established safe harbors and exceptions to the anti-kickback statute, which can shield a relationship from liability on both the state and federal level. There is a parallel anti-kickback safe harbor for space rental that is similar to the Stark Law exception. This safe harbor is roughly the same as the exception except that the *aggregate* rental payments must be set in advance, as opposed to the comparable Stark Law exception that permits variable or "per click" rental payments. Therefore, to meet the safe harbor, the to-

...whenever health care providers have financial dealings, the relationship must be analyzed under the relevant federal and state laws governing health care fraud and abuse.



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tal rent paid must be determined at the beginning of the rental period. Again, failure to meet the safe harbor does not mean that the lease is illegal, only that the arrangement will not enjoy the shelter of the safe harbor.

COMMENTARY

Is it reasonable to require physicians and hospitals to meet such rigid requirements in establishing office space relationships? Even Pete Stark acknowledged that patients benefit from having their doctors at the same location as the hospital that may provide laboratory, x-ray or other outpatient services. Additionally, the proximity of the doctor to the hospital may permit faster response in emergencies. The constraints placed on these leases make bargaining more protracted and rents artificially depressed when many hospitals are having a difficult time simply covering their operating costs. But regulators and Congress are concerned that the presence of the financial relationship between the parties could cloud their judgments and cause patients to be referred for unnecessary, costly, painful or even dangerous tests without sound medical justification.

One might ask whether there are not more efficient methods of policing the evils these laws are designed to prevent without imposing such requirements. For example, hospital medical staffs, the Board of Medical Licensure and Discipline, PRO, or patient advocates are far better safeguards to prevent the impairment of physician objectivity by the profit motive. Nevertheless, hospitals and physicians should be conscious of

the laws that regulate their relationships. In the meantime, the industry should consider approaching Congress and the regulators to seek the reform of the more onerous and unreasonable requirements.

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3. *Introduction of the Ethics in Patient Referrals Act*, 101st Cong., 1st Sess., 135 Cong. Rec. H. 240, 242 (February 9, 1989).
4. SSA § 1877(e)(1)(A). Note that HCFA may impose additional requirements on these leases, although it has not clearly done so to date.
5. *Cf.*, 42 Fed. Reg. 63518, 63526 (November 19, 1999) "Clarifications" to anti-kickback safeharbors.
6. 42 U.S.C. § 1320a-7b(b).
7. R.I.G.L. § 5-48.1-1 *et seq.*

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Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report

Provisional Occurrence Data
from the
Division of Vital Records

Underlying Cause of Death	Reporting Period			
	Jan. 1999	12 Months Ending with Jan. 1999		
Diseases of the Heart	302	Number (a)	Rates (b)	YPLL (c)
Malignant Neoplasms	238	3,090	312.1	3,648.5
Cerebrovascular Diseases	57	2,495	252.0	6,575.5**
Injuries (Accident/Suicide/Homicide)	31	590	59.6	823.5
COPD	53	361	36.5	6,857.5
		445	44.9	352.5

Vital Events	Reporting Period		
	July 1999	12 Months Ending with July 1999	
	Number	Number	Rates
Live Births	1,050	13,280	13.4*
Deaths	863	9,798	9.9*
Infant Deaths	(5)	(84)	6.3#
Neonatal deaths	(4)	(64)	4.8#
Marriages	928	7,667	7.7*
Divorces	185	3,030	3.1*
Induced Terminations	395	4,820	363.0#
Spontaneous Fetal Deaths	98	1,032	77.7#
Under 20 weeks gestation	(94)	(959)	72.2#
20+ weeks gestation	(4)	(73)	5.5#

**Excludes one death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population

Rates per 1,000 live births

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NINETY YEARS AGO

[JANUARY, 1910]

In "The Treatment of Tuberculosis," Jay Perkins, MD, decried the enthusiasm - bordering on fads - for single strategies. For instance, he valued fresh air ("Nature first created an atmosphere about the earth and then created a human being to live in that atmosphere... Hence...the air as it is found free in nature is the proper air to breathe... Nature did not give the atmosphere as found in ... unventilated sleeping rooms, factories, workshops, schools, ... or overheated living rooms.") Yet he pointed out the dangers of cold air. Similarly, he stressed proper nourishment, but warned, "Many digestions have been ruined simply by the fetish of milk and eggs." As for rest, he cited excessive rest, with insufficient exercise, as "one of the failures of sanitarium treatment": patients were discharged home cured of their disease, but "incurable as to their value to society, all through the exaggeration of the rest cure."

F.P. Gorham, PhD, explained the state's decision to test cows for bovine tuberculosis in "A Clean Milk Supply for the State Sanitarium." Burrillville dairy farmers Messrs. T.H. and A.E. Sweet supplied the Wallum Lake facility with milk, which the state had judged of high quality. The cows, though, had not been given a tuberculin test, in part because experts differed on the need (some believed that bovine tuberculosis was only rarely passed to humans; others, that 23% of all human tuberculosis came from infected cows), in part because farmers feared the loss of as many as three-quarters of their herds. In September the state decided to submit all cows to the tuberculin test. October 26, the state Veterinarian tested Messrs. Sweet's 46 cows. Twenty-six tested positive; on autopsy, every one was infected. Dr. Gorham concluded, "...whether the milk from tuberculous cattle is a factor in the spread of human tuberculosis or not, none of us wants to use...milk from sick cows."

In the public schools, a physician examined children and generally referred those who needed care to a hospital. The Medical Society Committee on Medical School Inspection polled members on the practice. Of 106 physicians surveyed, 55 wanted to discontinue the practice; and 15 "so qualified their yes as to make it a negative." Forty-five reported that they lost patients. One member wanted only "the abject poor" to be referred to the hospital. He objected, moreover, to nurses doing anything remotely medical: "As for a nurse expressing an opinion as to the treatment or giving advice or instruction, she should be dismissed at once."

FIFTY YEARS AGO

[JANUARY, 1950]

Physicians from a small primary care group practice (John Fallon, James Brosnan, William G. Moran, John Meyers, Elizabeth Fletcher) described "Endometriosis: A Report of 400 Cases" - a condition they concluded was "widespread," with extraordinary variation in type ("We have seen gastric, cholecystic, and appendiceal as well as the common intestinal lesions"). The authors discussed differing perceptions of the importance of endometriosis ("One asks, 'What's a little endometriosis among friends?' Another castrates every patient.").

In "Metastatic Calcification and Renal Failure Following Ertron Therapy in an Aged Arthritic," Harry Hecker, MD, traced the first use of ertron in patients with arthritis to a chance discovery: a patient treated with vitamin D for an allergy experienced alleviation of his arthritis. The therapy, though, had toxic effects. In this case, a 70 year-old man had for four years suffered from "arthritis of the upper extremities and ankles, with deformities of the hand." He was treated with 12 capsules of Ertron (50,000 units/capsule) a day for months, then 6 daily for over a year. He was admitted to the hospital with widespread calcifications in various soft tissues and "haziness" over the right lung. After 13 days of penicillin, his lung x-rays were clear.

In "Aureomycin in the Treatment of Pemphigus," Peter J. Mathieu, MD, discussed the treatment of a 76 year-old salesman, who entered the dermatological service at Rhode Island Hospital "with a bullous eruption involving the entire body surface." His skin had been clear until 6 months previously. Treatment consisted first of 306 roentgen units over 6 days, 3 grams sulfapyridine daily for 5 days, and .25 gram acetarsone for 1 day. The man did not improve. Subsequent treatments included a paraffin spray applied to the body 3 times a day for 11 days, 2% gentian violet in water injected into the bullae, a high protein pureed diet, and 3 milligram tablets (50,000 units) Vitamin D daily. Again, the patient did not improve. Physicians then started aureomycin: 1 gram by mouth every 6 hours for 24 hours, gradually decreasing. After 13 days the bullae had disappeared. After 16 days the patient was rational, alert, with appetite restored. Physicians stopped the aureomycin. Bullae reappeared. Therapy resumed. Bullae disappeared. And re-appeared when therapy stopped. As an alternate, the patient was put on chloromycetin, but showed no remission. Finally, "following 98 days of hospitalization, patient was discharged to a convalescent home in good health," on a maintenance dose of 8 capsules of aureomycin daily. The patient felt fine.

An editorial explained the AMA decision to assess members of the Association \$25, after 100 years "without any financial obligation to the parent body."

TWENTY FIVE YEARS AGO

❖ [JANUARY, 1975] ❖

In "Message from the Dean," Stanely M. Aronson, MD, discussed "CME Resources for the Practicing Rhode Island Physician." The Rhode Island Health Science Education Council, Brown University, and the Rhode Island Medical Society had formed an integrative unit for CME. Its Coordinating Committee had begun to hire staff and set up an office.

Hannibal Hamlin, MD, in "A Look at Romanian Health Care Organization-Education-Practice," commented on his federal HEW-funded trip. He found "...despite conflicting political ideologies and major societal differences over health-care organization and delivery in [Romania] and US, the majority of [professionals]...seem committed to what could be accepted as a Galenic axiom. *Sana aegros quam optime* (Heal

the sick as best you can.)

Chong Kong, a Brown University medical student, contributed "Cystinosis: Review," a discussion of intracellular deposits resulting in renal damage and ultimately in uremia, "a rare hereditary disorder."

Sewell J. Kahn, MD, contributed "The Nephrotic Syndrome," discussing the diagnosis, presentation, and therapy.

An editorial ("Health Care Crisis") cautioned that "Radical change is long overdue" for malpractice insurance. In New York state, one insurer withdrew from the market, and a new one wanted a rate increase of 196.8%, "effective immediately." The editorial noted, "It is possible for a new orthopedic surgeon to be faced with paying more insurance premiums in his first year than he could earn in his first few years of practice." (The New York State Insurance Commissioner had suspended the new rates, pending a hearing.) The problem was looming in 7 other states.

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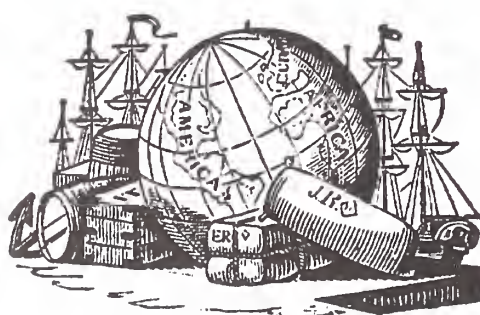
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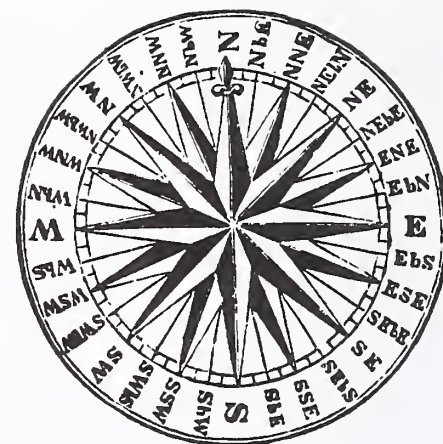


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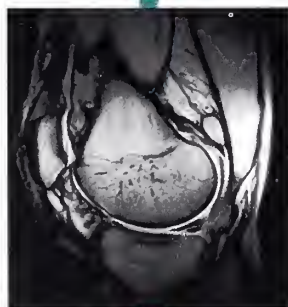
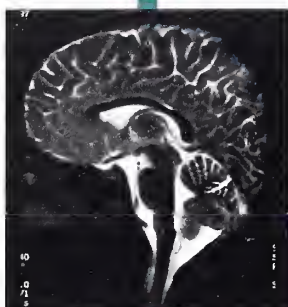
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No Brainer

As you see, there are no articles on boxing injuries in this issue devoted to sports injuries. This is because sports medicine specialists don't treat most boxing injuries. Most boxing injuries are in the domains of neurology and neurosurgery. Boxing is the only popular sport in which the sole aim is to injure the opponent, preferably by "knockout," which obviously means concussion. Blows to the head are never a good thing for the brain, other than for that rare "learning experience." To subject one's brain to repeated blows requires a good reason.

Apologies for boxing invariably focus on the economic aspects. Poor and emotionally troubled youths are given a theoretical ticket out of their poverty. The truth, of course, is that earning this ticket is not much more likely than winning a lottery, but requires years of effort, physical suffering and an almost impossible handicapped contest with a corrupt and venal establishment. It is a rare individual who makes it through intact.

The risks are real. While it is rare for a boxer to die as the result of an acute brain injury, it does occur, even

to fit, seemingly healthy boxers. We see cases like Stephan Johnson, a young man ruled unsafe to box in one state but safe to box in New Jersey, where he died as the result of head injuries from a boxing match. After all, boxing is good for casinos and casinos are good for New Jersey, or at least some people in New Jersey.

The major neurological sequelae of boxing are not acute. They occur many years later. Dementia pugilistica is not a diagnosis relegated to historical interest. It is becoming less common with some regulation of the boxing industry but it still occurs and is, like most brain insults, untreatable. It has become an interesting research focus as certain risk factors, like the apo E 4 gene, which is a risk factor for Alzheimer's disease, has been found to also be a risk factor for this condition. But can you imagine a boxing commission reducing the number of matches of a boxer based on genetic testing? More interesting still is the fact that dementia pugilistica is a progressive



disorder that begins and then worsens years after the last blow to the head. That is, repeated head blows, subconcussive as well as concussive, trigger a cascade of events culminating decades later in a progressive neurodegenerative disorder. Generally when we find the causes for diseases we try to stop them.

In a Woody Allen movie a character, when threatened with a brain procedure, declared that the brain, "is my second most favorite organ." It might even be number one for many, certainly near the top for all of us. It would be appropriate as this "decade of the brain" ends that we take a tiny stride forward in defense of healthy brains by banning this sport before too many more lives are damaged.

— Joseph H. Friedman, MD

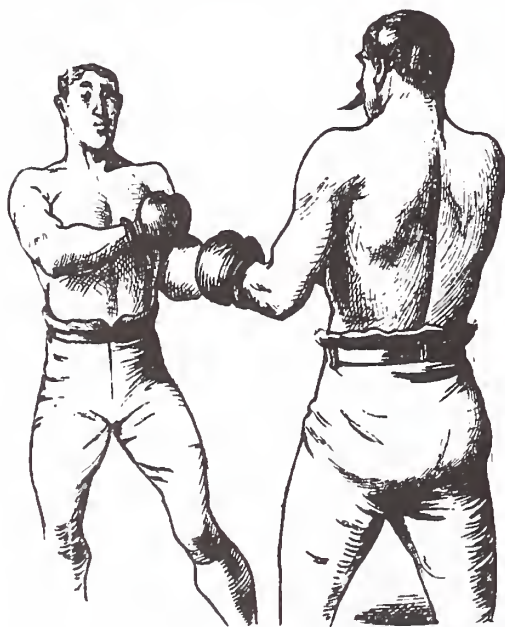
A Wondrous Thing, a Ray of Hope

How did it happen? How was the miraculous discovery of X-rays accomplished? It happened, say some history books, as a stroke of luck because a tenacious physicist was color-blind. Perhaps, but luck - or chance - as Pasteur once observed, selectively favors the prepared mind.

Wilhelm Konrad von Roentgen was born in the west German village of Lennep, in the year 1845, the offspring of a well-established mercantile family, a branch of which had been famed for its excellence in furniture manufacture. [One ancestor was cabinet-maker to Marie Antoinette.]

Shortly after Wilhelm's birth the family moved to Holland, where he lived until college age. He then attended the eminent technical institute in Zurich where, decades later, Einstein was similarly educated. After receiving his doctorate degree, Roentgen held a succession of academic posts in Germany until 1885, when he was appointed Director of the Physical Institute of Wurzburg University, Bavaria.

Roentgen was described as a tireless, some said compulsive, experimentalist. His personal laboratory was on the floor directly below his living quar-



ters and he customarily adjourned to his research activities immediately after each evening meal.

In the later decades of the 19th Century, German physicists had been exploring the potentialities of a newly invented contrivance called the cathode ray tube. When activated, it emitted invisible rays [later shown to be streams of electrons] which affected certain measuring instruments. These cathode rays were capable of travelling almost a meter.

Roentgen had built his own cathode ray tube powered by a pulsating electrical current amplified by a large induction coil. Prior investigators had demonstrated that when a flat plate, coated with a barium platinocyanide compound, was exposed to an activated cathode ray tube, it glowed with a curious greenish fluorescence. Roentgen, color-blind, could not discern the faint green emanating from the barium-coated plate. Accordingly, on the evening of November 8, 1895, he darkened his laboratory completely, even surrounding his cathode ray tube with black cardboard, thus making it light-tight. On the laboratory table, more than two meters from the activated cathode ray tube, lay a scrap of paper upon which a graduate student had, in an idle moment, painted the initial "A" using a barium solution. To Roentgen's astonishment, the letter "A" now glowed vividly in the darkness despite the cardboard barriers which should have blocked any conventional light rays and despite its considerable distance from the cathode ray tube.

Roentgen then directed his energies to determine the nature of his unique discovery, spending weeks in his laboratory without respite. He ascertained, first, that the mysterious rays which caused the barium plate to glow were distinguishable from cathode rays. Furthermore, these mysterious rays [he was, at first, unable to characterize their physical nature and hence he called them "X" rays] easily penetrated dense objects such as wood, books, playing cards and even thin sheets of metal; but not all metals. He noted that lead, beyond a certain thickness, blocked the passage of X-rays. These newly discovered rays shared certain properties with visible light: Both types of ray, for example, could darken photographic film. But, in contrast to visible light, X-rays could be neither reflected nor refracted. And they differed from cathode rays in being indifferent to the forces of magnetism. To Roentgen's astonishment, when X-rays were allowed to radiate a closed wooden box containing various metallic objects, the activated barium plate revealed the outlines of these inner objects; and, if a photographic film were substituted for the fluorescent plate, a permanent record of these metal objects could be made. A few days before Christmas of 1895, Roentgen invited his wife, Bertha, into the laboratory to inspect his discovery. He interposed Bertha's hand between the X-ray source and an unexposed photographic plate. The resulting picture - now immortalized in countless medical texts - showed not only the bold outline of Bertha's wedding ring but also the contours of her underlying hand bones.

Within days, Roentgen submitted a brief descriptive paper to a scientific journal; and to his amazement, the news of his serendipitous discovery moved swiftly from the intimate community of academic physicists to the general public, with electrifying results. Newspapers around the world heralded the discovery and its obvious implications for diagnostic medicine. The *New York Times* declared it to be an invention of unparalleled significance. Rarely in the history of scientific progress had an arcane laboratory finding moved so rapidly to the realm of practical application. By February 22, 1896, fifty days after Roentgen's first publication, the British medical journal, *Lancet*, published a paper urging surgeons to use X-rays to locate bullets. It was indeed no exaggeration when historians pronounced Roentgen's discovery to be the equal of such 19th Century advances as the newly established science of bacteriology, the invention of inhalant anesthesia and the devising of effective vaccines.

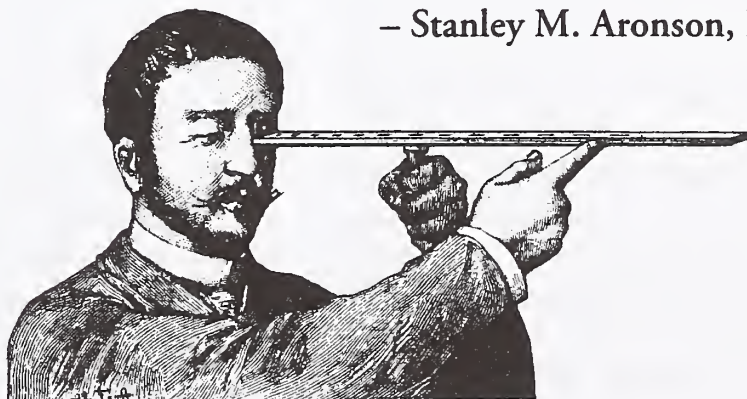
But the advent of X-rays led also to bizarre proposals and baseless anxieties. Some urged that X-rays be employed to clarify the location and characteristics of the human soul. Others, of a modest nature, feared that the penetrating X-rays might invade their privacy, perhaps involuntarily exposing their feral passions. One haberdasher in late Victorian London even advertised underclothing that blocked the inquisitive probings of X-rays.

Within five years of this monumental discovery, crude X-ray machines were constructed in many nations. In the United States the resulting films were called skiagrams [from the Greek, meaning shadow-pictures.] In the Spanish-American War, military surgeons were using X-rays to disclose the locations of penetrating bullet fragments.

Roentgen was awarded the very first Nobel prize in physics in 1901. He quietly continued investigations of his mysterious rays for another 22 years. His life's companion, Bertha, died in 1922 and a grieving Roentgen passed away shortly thereafter.

Because a color-blind Roentgen could not discern a faint greenish glow in subdued light, he repeated his experiments in a totally darkened room. But it was his alert, prepared mind as much as luck that allowed him to convert a chance observation into the discovery of a heretofore unrecognized form of ray. These Roentgen rays had the unique property of exhibiting, on photographic plates, the relative densities of the opaque objects through which they passed; and medicine's capacity to identify internal disease then took a giant step forward.

— Stanley M. Aronson, MD



Arrhythmias in Athletes

Robert Lemery, MD

Arrhythmias in athletes represent a particularly challenging aspect of cardiovascular medicine. Although occasionally the athlete may have a personal or family history of cardiovascular disease, in the majority of cases tachyarrhythmia disorders develop¹⁻³ because a condition already existent becomes manifest due to sport activities (i.e. a concealed accessory pathway is the cause for paroxysmal supraventricular tachycardia). Or the athlete may become symptomatic due to more specific pathophysiologic changes related to intense exercise.¹ Sudden cardiac death occurring during athletic performances, in individuals who are in top shape, remains the most feared and terrifying aspect of arrhythmias in athletes.

SYMPTOMS, PREEXISTING CONDITION, FAMILY HISTORY

The three main cardiovascular symptoms that require concern are palpitations, syncope, and chest pain. Although the relation between symptoms and exertion is obviously important, their occurrence at rest should not be ignored. Palpitations caused by premature ventricular contractions often decrease during exertion only to reappear during recovery, or patients may be symptomatic while resting in the late evening. Supraventricular tachycardia can occur during exertion, but in most patients, brief or prolonged episodes of tachycardia will also occur at rest. Syncope (defined as loss of consciousness and postural tone, with spontaneous and complete recovery after a brief duration) of cardiac origin represents a difficult problem, especially in the athlete. Patients with the common faint (vaso-vagal, neurocardiogenic syncope) usually have a remote history of syncope; it is often recurrent and fairly characteristic in its presentation. In these patients, syncope can be exercise-induced but more commonly will occur following peak exertion. Most importantly in all patients with syncope, neurocardiogenic syncope remains a di-

agnosis of exclusion. Every effort should be made, by the detailed history, physical examination and noninvasive work-up, to exclude any underlying cardiac arrhythmia. Chest pain, either typical or atypical in its presentation, can be caused by myocardial ischemia related either to insufficient supply (coronary atherosclerosis or congenital coronary anomaly) or increased demand or other reasons (cardiomyopathies, ventricular hypertrophy, or valvular heart disease). Congenital heart block is usually associated with resting junctional bradycardia, but there is usually an excellent increase in junctional rate with exertion. These patients may become symptomatic or develop compensatory cardiac dilatation and/or abnormalities of the QT interval.

Assessment of risk factors should also be included in the patient's evaluation. Significant disorders of lipid metabolism may induce obvious dermatological abnormalities such as xanthomas, i.e. cholesterol-filled nodules either seen subcutaneously or over tendons. A family history of sudden cardiac death, especially under 50 years of age, increases the likelihood that the patient may be at increased risk of ischemic heart disease, hypertrophic cardiomyopathy or other cardiovascular disorders.

GENDER AND RACE

Female athletes, compared with male athletes, have a significantly lower risk of sudden cardiac death.¹ Multiple explanations include: the lower incidence of underlying heart disease (hypertrophic cardiomyopathy, ischemic heart disease), the fewer females involved in competitive sports, possibly protective effects of estrogen or relative lack of testosterone, and lesser amounts of cardiac dilatation or hypertrophy caused by exercise. Female athletes who present with symptomatic tachycardia or syncope require the same evaluation and treatment as in males. In addition, particular emphasis in the history should be given to men-

Abbreviations Used:

ECG	electrocardiogram
QT	Q-T interval
SVT	supraventricular tachycardia
VT	ventricular tachycardia
WPW	Wolff-Parkinson White Syndrome

strual periods. Excessive blood loss can lead to anemia; amenorrhea may be related to weight loss, which can be exacerbated by fasting or diet pills, with risk of repolarization abnormalities and cardiac arrhythmias.

Black athletes may be at increased risk of sudden cardiac death,¹ due to the occurrence of hypertrophic cardiomyopathy or left ventricular hypertrophy caused by hypertension.

SUPRAVENTRICULAR ARRHYTHMIAS

Supraventricular tachycardia (SVT) with a normal resting 12-lead ECG is caused by atrioventricular nodal reentry in 60% of cases, by atrioventricular reentry caused by concealed (i.e. not manifest on the 12-lead ECG - no delta wave) accessory pathway in 30%, while atrial tachycardia occurs in approximately 10%. Enhanced adrenergic tone associated with exertion can be a particularly strong stimulus for tachycardia induction (the equivalent of administering isoproterenol to provoke SVT in the electrophysiology laboratory). In fact, the rate of tachycardia under isoproterenol has been shown to be similar to the rate of the actual clinical tachycardia.⁴ Palpitations, chest pain, shortness of breath and syncope can all occur. Tachycardia typically terminates either spontaneously, following Valsalva maneuvers, or after intravenous adenosine or verapamil (in atrial tachycardia, intravenous beta blockers or calcium blockers are generally required).

WOLFF-PARKINSON WHITE SYNDROME (WPW)

Athletes with WPW can also develop atrioventricular reentry tachycardia, as outlined above, requiring the same therapeutic approaches. However, the important distinction in patients with WPW is the potential for rapid conduction over two pathways (the normal atrioventricular node and the accessory pathway). Because patients with WPW are at increased risk of developing atrial fibrillation,⁵ athletic performances that usually result in an increase in catecholamines may lead to enhanced atrioventricular conduction, as well as a decrease in the refractory period and increase in 1:1 conduction over the accessory pathway. These factors can cause tremendously rapid ventricular rates during atrial fibrillation, and specific groups of patients with WPW have been identified who are at high risk for developing ventricular fibrillation (shortest R-R interval of pre-excited beats < 200-250 msec, patients with multiple accessory pathways and, to a certain extent, persistence of pre-excitation during non-invasive testing or administration of a class IA antiarrhythmic agent).

ATRIAL FIBRILLATION OR FLUTTER (NOT RELATED TO WPW)

Paroxysmal atrial fibrillation, generally called lone atrial fibrillation when there is no underlying heart disease, or atrial flutter, can be a great nuisance to the athlete. Often, the precise initiating mechanism is unclear, i.e. whether the episodes are vaguely mediated, or occur following a sympathetic surge. Generally, patients are symptomatic or their performances are sub-par. Most patients have spontaneous conversion to sinus rhythm, but pharmacological or electrical DC cardioversion may be required. In addition, warfarin, given to prevent cardiac thrombus formation, may be associated with an increased risk of bleeding complications related to trauma during exercise activities.

TREATMENT OF SUPRAVENTRICULAR ARRHYTHMIAS

There are three main limitations to use of antiarrhythmic agents to prevent supraventricular arrhythmias. First, the

side effects of these agents, especially beta blockers, on exercise performance are a real concern for the athlete. Second, the favorable effects of antiarrhythmic agents are often reversed or negated by enhanced adrenergic tone, so that the athlete may not be protected when he most needs it, i.e. during exercise. Finally, the rate dependency of antiarrhythmic agents,⁶ i.e. their increased effects when the heart rate increases, can increase the risk of pro-arrhythmia^{6,7} (which may result in ventricular tachycardia or ventricular fibrillation). Radiofrequency ablation remains the treatment of choice in the symptomatic athlete with supraventricular arrhythmias, and is also occasionally indicated in the asymptomatic athlete (example, presence of a delta wave on the resting ECG without associated symptoms but with characteristics for rapid ventricular conduction). Hopefully, new approaches to radiofrequency ablation of atrial fibrillation, by targeting the focal areas responsible for initiating atrial fibrillation (usually atrial premature beats originating in the pulmonary veins), will help decrease the morbidity associated with atrial fibrillation.

VENTRICULAR ARRHYTHMIAS (NON-ISCHEMIC RELATED DISORDERS)

Premature ventricular extrasystoles and non-sustained ventricular tachycardia (VT) can occur in the normal heart.⁸ Most often, when the patient is asymptomatic, reassurance alone is sufficient. However, in the athlete ventricular arrhythmias associated with or without symptoms represent a difficult problem because of the risk of sudden cardiac death. In many cases, the resting 12-lead ECG is abnormal and the 2-D echocardiogram may show chamber enlargement. During assessment of ventricular ectopy, the morphology, rate and duration of extrasystoles are important and may help guide the approach to therapy.

VENTRICULAR EXTRASYSTOLES SHOWING A LEFT BUNDLE BRANCH BLOCK APPEARANCE IN V1

In most of these patients, ventricular extrasystoles originate from the right

ventricle. In the so-called benign form of VT⁸ the ventricular extrasystoles or VT usually show an inferior axis and short repetitive runs are often present, typically with a gradual increase in the cycle length of VT (slower rate during the latter beats of VT). In patients who do not have an inferior axis, and in whom VT is more sustained and often more rapid, arrhythmogenic right ventricular dysplasia should be ruled out.^{9,10} This can be difficult in some patients, but most often abnormalities of repolarization are present in the precordial leads V1-V3, showing an epsilon wave on rare occasions, or more commonly T-wave inversion. The 2-D echocardiogram or the MRI may show abnormalities of the right ventricle, including enlargement, wall thinning and saccular aneurysms. The majority of patients with arrhythmogenic right ventricular dysplasia are males; atrial tachycardia, flutter or fibrillation occur in 25% of patients.

In athletes with non-ischemic repetitive VT, originating from the right ventricle who have suppression of their arrhythmia during exercise testing, specific treatment is usually not required unless patients are symptomatic. In athletes with more sustained VT, programmed ventricular stimulation in the electrophysiology laboratory can be used to guide treatment. Although beta blockers are often administered to patients with these forms of VT, their effectiveness is usually very limited and more specific antiarrhythmic agents are often required. Sotalol®, a class III antiarrhythmic agent with beta-blocker activity (this drug does not have rate-dependent properties), is the treatment of choice in patients with non-ischemic VT originating from the right ventricle.¹¹ Radiofrequency ablation can be effective at eliminating the site of origin of VT, but the procedure can be of limited value in patients who do not have inducible VT during programmed ventricular stimulation (i.e. VT cannot be mapped), or in patients with arrhythmogenic right ventricular dysplasia in whom there are often multiple origins of VT. In these patients, implantation of a defibrillator may be required (for example, a professional basketball player in the NBA with

arrhythmogenic right ventricular dysplasia who has a defibrillator).

VENTRICULAR EXTRASYSTOLES SHOWING A RIGHT BUNDLE BRANCH BLOCK APPEARANCE IN V1

Sustained uniform VT showing a right bundle branch block morphology and left axis deviation, occurring typically in males without any significant abnormalities on the ECG or 2-D electrocardiogram, is usually secondary to VT originating from the apical septum of the left ventricle.⁸ This form of VT, typically considered benign, responds well to verapamil (intravenous or oral). Radiofrequency ablation is usually curative in up 90% of patients. However, patients showing VT with a right bundle branch block appearance may also have VT originating from other sites (basal, free wall), often occurring in areas of dilatation or hypertrophy, and radiofrequency ablation may be significantly more difficult.

POLYMORPHIC VT/OTHER FORMS OF VT

Non-sustained or sustained VT, or more specifically *torsades de pointes*, can occur in patients with the long QT syndrome. There is a congenital form that is usually adrenergic-dependent. Patients may present with neural deafness - Jervell and Lange-Nielsen syndrome (autosomal recessive) or without any neurologic deficit (Romano-Ward, autosomal dominant), or be nonfamilial and sporadic. Another form, the acquired pause-dependent type, may occur under a variety of stimuli, including electrolyte and dietary disorders, heart disease, sinus node dysfunction, and exposure to drugs such as certain antiarrhythmic agents, antimicrobials, antihistamines¹² or cocaine. Patients with abnormalities of the QT interval require avoidance of exposure to the offending stimuli, and various therapeutic options include treatment with beta blockers, permanent pacing or defibrillator implantation.

Patients with VT associated with a short coupling interval of the first ventricular extrasystole, may develop sustained uniform or polymorphic VT, and some of these patients have previously

been described as having idiopathic ventricular fibrillation.¹³ Recent data suggest that some of these patients may have a mutation of the cardiac sodium channel gene, SCN5A, responsible for the early repolarization aspect in V1 (so-called Brugada syndrome).¹⁴⁻¹⁷ Most of these patients require implantation of a defibrillator.

Among the causes of sudden cardiac death in young competitive athletes, hypertrophic cardiomyopathy is the most common cardiovascular abnormality, accounting for one-third of all deaths.



SUDDEN CARDIAC DEATH AND STRUCTURAL HEART DISEASE

Sudden cardiac death in the athlete is rare, but its occurrence is extremely distressing, with psychological and psychosocial implications. The three following events offer striking examples. A young teenager, playing goalie for his hometown hockey team, dies suddenly after making a routine save during a competitive game, and was found to have arrhythmogenic right ventricular dysplasia. A top athlete, young college prospect, dies suddenly during a basketball game shown on national television, and the autopsy reveals focal myocarditis. More recently, an Olympic figure skating medallist dies suddenly during a practice session, and was found to have severe coronary artery disease. Of these three individuals, the second had a history of VT, and had reduced beta blockade treatment due to side effects that impaired the athlete's performance. In the third example, risk factors for coronary artery disease were present. However, in the first example, there was no hint of any cardiac abnormality.

In athletes who present with symptomatic or asymptomatic supraventricular or ventricular arrhythmias, or syncope (especially exercise-induced), exclusion of

any underlying structural heart disease remains of utmost importance. Physical examination, a 12-lead ECG and 2-D echocardiogram should be obtained, while holter recordings, use of loop monitor and exercise testing may be useful to guide therapy. Radiofrequency ablation is usually the treatment of choice in athletes who have symptomatic SVT or VT. An implantable defibrillator is usually mandatory in individuals who have been successfully resuscitated from an episode of sudden cardiac death, or in others who are at high risk (history of polymorphic VT, idiopathic ventricular fibrillation - Brugada syndrome, malignant forms of arrhythmogenic right ventricular dysplasia).

HYPERTROPHIC CARDIOMYOPATHY

Among the causes of sudden cardiac death in young competitive athletes, hypertrophic cardiomyopathy is the most common cardiovascular abnormality, accounting for one-third of all deaths.¹ Standard screening procedures, using the personal or family history as well as physical examination, cannot reliably or consistently identify the presence of ventricular hypertrophy. Patients with hypertrophic cardiomyopathy who are at high risk of sudden cardiac death include those with a history of sustained VT or aborted sudden cardiac death, non-sustained VT during holter monitoring, a history of syncope, a family history of sudden cardiac death associated with hypertrophic cardiomyopathy, and extensive left or right ventricular hypertrophy. Interestingly, in patients with hypertrophic cardiomyopathy who are not athletes, the occurrence of sudden cardiac death shows a bimodal pattern of circadian variability over the 24-hour day. However, athletes with hypertrophic cardiomyopathy show a predilection for sudden cardiac death during the late afternoon or early evening hours, identical to sudden cardiac death in athletes without hypertrophic cardiomyopathy, which strongly suggests the importance of physical exertion as a trigger for sudden cardiac death.^{1,18}

SCREENING GUIDELINES

Accepted athletic pre-participation cardiovascular screening evaluation¹⁹ in-

cludes obtaining a complete medical history and physical examination (including dynamic maneuvers to identify heart murmurs) before participation in high school and college sports. In the high school athlete, screening is done every two years, while in the college athlete, a yearly history and blood pressure measurement should be obtained. Neither the ECG nor the echocardiogram has been shown to be cost effective or to efficiently enhance screening evaluation. In individuals older than 35, whether they are athletes or not, sudden cardiac death is usually secondary to coronary artery disease and screening for risk factors is essential.

IMPORTANCE OF CARDIOPULMONARY RESUSCITATION AND AUTOMATIC DEFIBRILLATORS

Ultimately, the most effective measures to reduce the risk of dying suddenly in asymptomatic athletes are to: 1) reduce the risk of injury associated with the sport - such as wearing better neck and chest padding in young hockey players and 2) provide automatic external defibrillators and have individuals trained in cardiopulmonary resuscitation at sports facilities. The cost of these portable defibrillators is \$3,000. In one study of 115 athletes with sudden cardiac death who had undergone standard screening tests, 3% showed symptoms of heart disease and less than 1% were correctly diagnosed.¹ Therefore, identification of the asymptomatic athlete, or absolute protection in the treated symptomatic athlete, remains extremely difficult. A recent study suggested that for spectators attending major athletic events the additional cost per ticket would be less than a nickel to provide at each stadium 50 individuals trained in cardiopulmonary resuscitation and 25 automatic external defibrillators.²⁰

A recent study suggested that for spectators attending major athletic events the additional cost per ticket would be less than a nickel to provide at each stadium 50 individuals trained in cardiopulmonary resuscitation and 25 automatic external defibrillators.



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Diagnosis and Nonoperative Treatment of Common Athletic Shoulder Injuries

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Athletes participating in contact or repetitive overhead sports are prone to shoulder disorders. The incidence of injury varies across types of sports as well as with level of athletic competition and the athlete's age. Shoulder problems are the most common musculoskeletal complaint in swimmers and are also reported with high frequency in football, baseball, golf, tennis and other overhead athletics.¹ Although shoulder problems continue to be a common complaint in older athletes, the differential diagnosis changes with age-related degeneration of musculoskeletal tissues. Full thickness tears of the rotator cuff are rare in young athletes, but more common with increased age (e.g., senior tennis players). This article reviews the current evaluation and treatment of common shoulder injuries in both the younger and older athlete.

CLASSIFICATION

The shoulder's anatomy, built more for function than stability, makes it susceptible to injury. Trauma to the shoulder girdle, causing acute injury to previously normal tissues, forms one group of athletic shoulder disorders. These macro-traumatic injuries are most frequent during collision sports and result in injuries such as glenohumeral dislocations, acromioclavicular joint sprains, glenoid labrum and rotator cuff tears.^{2,3} The second group consists of the chronic overuse type disorders in which repetitive micro-traumatic injuries result in the gradual overload and failure of tissues. These disorders are most frequent in the overhead athlete, such as a baseball pitcher, tennis player or swimmer, manifesting in a variety of conditions, most commonly rotator cuff tendinopathy and atraumatic glenohumeral instability.⁴

CLINICAL EVALUATION

The shoulder girdle is comprised of four joints - glenohumeral, acromioclavicular, sternoclavicular and scapulothoracic. When evaluating for shoulder complaints, each articulation must be considered as a source of pathology. Also, pain from cervical spine, thoracic, cardiac and intra-abdominal disorders can frequently be referred to the shoulder region.

Evaluation begins with a thorough history noting the onset and type of symptoms. Previous injuries or symptoms are often discounted by the athlete and must be elucidated by the physician. Pain is the most common presenting symptom. The location, timing and intensity of the pain can help delineate its cause. Rotator cuff tendinopathy pain occurs in the anterior shoulder, is frequently described as dull or aching and is also present at night. Pain associated with anterior shoulder instability is usually sharp and occurs in the region of the posterior capsule during the acceleration phase of the throw or stroke. Other complaints may be vague: the shoulder feels weak, the arm feels heavy or "goes dead", especially with glenohumeral instability. It is helpful to determine a precipitating event, whether an acute injury, a change in training intensity, or an associated injury (such as a knee or elbow injury) causing a change in throwing mechanics with increased stress at the shoulder. Discerning what type of activities exacerbate symptoms can also be helpful in making a diagnosis. For example, a football offensive lineman with posterior instability of the glenohumeral joint may have pain during pass blocking with the arm straight and shoulder flexed as the humeral head is driven over the posterior glenoid rim. The relation of pain to training and whether the symptoms interfere with sports, daily activities or

Abbreviations Used:

AC	acromioclavicular
AP	anterior-posterior
NSAID	non-steroid anti-inflammatory drug
MRI	magnetic resonance imaging

sleep can help determine treatment and predict recovery time. The patient's response to prior treatments including rest, anti-inflammatory medications and therapy, is also useful in diagnosis and treatment.

Examination of the athlete is performed in a setting that allows visualization of both shoulders. Otherwise, subtle findings such as atrophy or scapular winging will be overlooked. The contralateral shoulder is examined first to determine 'normal' parameters and a cervical spine exam is performed to evaluate for referred pain. The shoulder girdles are inspected for asymmetry. Muscle atrophy is pathologic while hemi-hypertrophy or shoulder girdle depression are sometimes seen in the dominant arm of throwers. The sternoclavicular and acromioclavicular joints are inspected and palpated. Provocative maneuvers for acromioclavicular joint injury include pain at the joint with resisted elevation at shoulder height and forced horizontal adduction. Active and passive glenohumeral motion are recorded in all planes noting associated pain, crepitation or clicking. Increased external rotation with concomitant loss of internal rotation can be normal in the throwing athlete. The apprehension and relocation tests are performed with the athlete supine and the shoulder in the 'at risk' position of abduction and external rotation. The examiner places forward pressure on the proximal humerus, levering the humeral head anteriorly, out of the glenoid fossa. The athlete may

complain of apprehension of impending dislocation or posterior shoulder pain. The examiner then applies posterior pressure on the proximal humerus while maintaining the athlete's arm in the position of apprehension. This maneuver prevents anterior subluxation of the humeral head, and relieves the athlete's apprehension or pain. Rotator cuff evaluation includes attempt to elicit the impingement sign, pain with full elevation of the shoulder while maintaining inferior pressure on the scapula. Rotator cuff strength testing includes resisted internal and external rotation, resisted elevation with internal rotation in the scapular plane. The examiner must be aware that some crossover exists in the physical examination findings between instability, rotator cuff disease and other painful disorders of the shoulder. Pain elicited by the apprehension and impingement maneuvers may be sensitive but not specific for instability and rotator cuff disease, respectively. Positive findings with these maneuvers are necessary but not sufficient criteria for diagnosis without supporting history and/or radiographic findings. In subtle or difficult-to-diagnose cases, multiple examinations may be required for an exact diagnosis. Frequently a local anesthetic injected into the subacromial space (Neer impingement test)⁵ or the acromioclavicular joint is helpful in elucidating the cause of pain.

Radiographs are essential to evaluate for fractures or dislocations, to assess for degenerative lesions, and to exclude rarer causes of shoulder pain (e.g. Pancoast tumor). Further radiographic work-up is rarely necessary during the initial evaluation and work-up for shoulder injuries.

SPECIFIC DISORDERS

Shoulder (Glenohumeral) Dislocation/ Subluxation

Anterior shoulder dislocation occurs from a fall or force being applied to the arm. The most common mechanism is excessive shoulder external rotation and extension, usually with the arm in the overhead position.

The athlete with a first-time traumatic dislocation will occasionally have

spontaneous reduction of the humeral head into the glenoid fossa. The shoulder usually remains dislocated and the athlete complains of extreme pain, especially with attempted arm movement, and frequently a feeling of arm numbness. A soft tissue sulcus is visible and palpable posteriorly as the humeral head is absent from its normal articulation with the glenoid. The athlete with an anterior shoulder dislocation holds his forearm away from the body as he cannot internally rotate and reach to touch the opposite shoulder. Associated nerve injuries need to be excluded with a thorough neurologic exam prior to intervention. True AP and axillary lateral radiographs are essential to document the direction of the dislocation and to rule out an associated fracture. If the x-rays do not demonstrate a fracture, reduction of the shoulder dislocation can be performed immediately. The presence of any fracture contraindicates attempted reduction and requires consultation with an orthopedist.

Many different reduction maneuvers for anterior shoulder dislocation have been described, including numerous traction/counter-traction methods. A simple maneuver is to have the patient relax in a sitting or lying prone position and to gently elevate the arm overhead.⁶ As the arm nears an overhead position, spontaneous reduction of the humeral head frequently occurs. This technique may be modified with the use of intravenous sedation or intraarticular injection of a local anesthetic. A post-reduction neurovascular exam is performed and radiographs obtained to document re-establishment of glenohumeral congruence.

After reduction, the patient is placed in a sling for comfort. When the athlete is able to tolerate movement, range of motion exercises are begun anterior to scapular plane. Extension, abduction, and external rotation are avoided to prevent recurrent dislocation. Rotator cuff, periscapular muscle strengthening are begun as pain diminishes. The athlete can return to sports when full motion and strength are achieved without apprehension in extremes of motion. A brace or restraint

that limits shoulder extension may prevent recurrent dislocation and allow an athlete to return to sports in the middle of a season.

The risk of recurrent dislocation is related to the degree of trauma necessary to produce the initial dislocation. Patients that are ligamentously lax or have a dysplastic glenoid fossa may dislocate with little trauma to the shoulder girdle and are at higher risk for recurrent injuries due to the inherent lack of stability to the glenohumeral joint. The best predictor for recurrence is patient age. Inversely proportional to age, the risk is reported as high as 94% in the under 20 group but drops below 15% at age 50.^{7,8,9}

Shoulder subluxation (transient partial dislocation) can be traumatic, atraumatic or voluntary. The athlete frequently is not aware of the abnormal movement of the shoulder and does not complain of instability. Instead, s/he feels that the arm goes dead, is heavy or weak with sharp posterior shoulder pain after forced external rotation in the overhead position.¹⁰ The symptoms can occur in a variety of overhead sports (throwing, swimming, or swinging a tennis racquet during a serve). During physical examination, instability may be mild and difficult to discern. The apprehension and relocation tests are sensitive but may not be specific. The physician makes the diagnosis based on history, examination and a high index of suspicion. Radiographs and MRI are occasionally diagnostic. Treatment with a shoulder rehabilitation program is frequently successful.



Rotator Cuff Tendinitis and Tears

Athletes performing highly repetitive activities, e.g., rowers and tennis players, or older patients may develop rotator cuff impingement syndrome,⁸ where progressive degeneration of the supraspinatus tendon from external compression of the anterior acromion and the coracoacromial arch manifests as a continuum from chronic bursitis and tendinitis to partial thickness or complete tears of the rotator cuff. Progression to full thickness rotator cuff tear with impingement syndrome occurs over a long period of time and is rare in the young athlete. The etiology of rotator cuff dysfunction in the younger athlete is more likely to be intrinsic or tension tendinopathy, presumably occurring in manner similar to that of other tendons that are placed under repetitive tensile stresses, eg. patellar tendinitis, achilles tendinitis and elbow epicondylitis. The shoulder, like these other regions, is thought to be susceptible to injury because of a tenuous blood supply at the rotator cuff insertion. Repetitive cycles of large forces generated and then dissipated during overhead activities place stress on the soft tissues of the shoulder girdle. The initial response to excessive stress on the rotator cuff and surrounding tissues is reversible inflammatory changes. With continued overuse, intrasubstance microtraumatic injury causes structural changes that act as a stress raiser. Atraumatic instability when present also disrupts the normal firing pattern of the rotator cuff and periscapular muscles as these structures also attempt to stabilize the humeral head. Progressive injury ensues and results in rotator cuff dysfunction and failure. Partial tearing of the undersurface of the rotator cuff can occur in association with anterior shoulder instability especially in the throwing athlete.¹⁴

Rotator cuff tendinitis causes pain, usually aching and occasionally sharp, in the anterior and lateral shoulder and arm. Initially pain occurs only during activity, then as the condition progresses, the athlete notes discomfort after workouts and at night. With further progression, pain begins to affect

performance and ultimately may prevent normal function. Examination may reveal tenderness at the anterior acromion and the coracoacromial arch. Most frequently, the athlete does not complain of weakness or loss of motion although both may be demonstrable on physical examination. Limited active and passive horizontal adduction occurs as a result of posterior capsule contracture, while pain may prevent full active elevation. Weakness of the rotator cuff may be subtle with the earliest findings being a loss of external rotation strength. Radiographs are typically normal but may demonstrate sclerosis and small cyst formation at the humerus greater tuberosity.

Radiographs are essential to evaluate for fractures or dislocations, to assess for degenerative lesions, and to exclude rarer causes of shoulder pain



Initial treatment focuses on relief of pain by limiting activity or modifying workouts, and administration of ice and nonsteroidal anti-inflammatory medications. As soon as pain will allow, a rehabilitative exercise program is begun, concentrating on capsular stretching and strengthening exercises. The majority of athletes treated in early stages will respond to these measures and return to sports without further treatment. Maintenance rehabilitation is continued throughout the season. When a patient fails to respond, s/he is reevaluated for other causes of pain that may have been overlooked, acromioclavicular joint arthralgia and subtle glenohumeral instability in particular. A subacromial injection of a water soluble corticosteroid with local anesthetic is performed for therapeutic effect as well as to confirm the diagnosis and the athlete is returned to a rehabilitative exercise program. This sequence is repeated twice over three to six months.



The young athlete's normal rotator cuff tendon is a thick multilayered collagenous structure that is extremely resilient and resistant to tearing. Direct contact injuries in this group rarely create full thickness cuff tears and are more likely to cause shoulder dysfunction as a result of rotator cuff contusion and traumatic subacromial bursitis.¹⁵ In older athletes, rotator cuff tears are generally a result of attrition from chronic subacromial impingement, with symptoms of pain and weakness beginning insidiously or suddenly from a fall. Tears most frequently occur at the supraspinatus tendon insertion at the greater tuberosity leading to pain with arm elevation above shoulder height (painful arc). Smaller tears may be difficult to differentiate from an acute exacerbation of cuff tendinitis and patients may maintain a full active range of motion. Larger tears result in more dysfunction with loss of active shoulder elevation but maintained passive motion. Weakness of the rotator cuff muscles is demonstrated with resisted external rotation and supraspinatus tests. MRI and ultrasound allow accurate and non-invasive imaging of the rotator cuff. Treatment rotator cuff tears in most active patients are surgical.

Glenoid Labrum Tears

The glenoid labrum is made of fibrocartilage, lines the glenoid rim, deepening and conforming the fossa to the humeral head. Tears due to degeneration and aging or as a result of trauma are a potential source of pain or catching within the glenohumeral

joint. In many instances, however, tears are not symptomatic and are incidental findings. The athlete with a labrum injury may complain of pain, catching or weakness, usually when the arm is in an overhead abducted, externally rotated position. If the tear is the result of a dislocation or subluxation, symptoms of instability may also be present. Physical findings are variable. Reproduction of the athlete's symptoms of painful clicking from the glenohumeral joint with range of motion and translation testing is the most consistent finding. Treatment of the athlete suspected of having a labrum tear is based on the tear pattern and presence or absence of glenohumeral instability. All patients are initially treated conservatively with a period of rest, anti-inflammatory agents and, if applicable, rehabilitative exercises.

Acromioclavicular (AC) joint sprain

Acute injuries of the acromioclavicular joint occur with direct contact to the shoulder with a fall or striking an object, or landing on an outstretched arm. The athlete complains of pain and difficulty raising an arm. This must be differentiated from injury to the rotator cuff, subluxation and burner syndrome (transient brachial plexopathy). Localized swelling and tenderness or deformity with joint dislocation lead to immediate diagnosis of these injuries. When the etiology of the pain is less obvious, provocative maneuvers such as forced adduction or resisted shoulder elevation will cause pain at the A-C joint. Occasionally, the joint is injected with xylocaine to aid in differentiating the cause of shoulder pain or weakness. Radiographs, obtained to evaluate for possible fracture, may demonstrate subluxation or dislocation of the AC joint. Weighted radiographs are rarely necessary since the diagnosis is largely made by history and examination.

Treatment of lesser AC joint sprains is conservative with rest, ice and anti-inflammatory medication, followed by rehabilitative exercises. Return to sports is allowed when pain and strength allow normal use of the extremity, with the athlete understand-

ing that reinjury may cause further ligamentous damage. The majority heal without sequelae. However, occasionally persistent limiting pain requires injection of a water-soluble cortisone preparation to diminish inflammation, repeated up to three injections over a three month period. More severe sprains with dislocation of the AC joint must be screened for associated neurologic injuries and should be evaluated by an orthopedist since treatment is controversial.

Fractures

Trauma to the shoulder girdle can result in fracture of the clavicle, scapula (including the glenoid fossa) or proximal humerus. Associated soft tissue injuries (e.g. neuropraxia, cuff tear) are not uncommon but frequently overlooked. Radiographic evaluation should include a minimum of a true AP and lateral view of the bone in question. Clavicle fractures are most frequently midshaft and are clinically obvious. Initial care includes evaluating the integrity of the overlying skin and deep neurovascular structures. The shoulder is immobilized in a sling, adding a swathe or figure-8 brace for comfort. Fracture of the upper humerus occurs in all age groups but is more frequent and disabling in older individuals. Patients with proximal humerus fractures require close evaluation with an axillary lateral x-ray to assess for concomitant dislocation of the shoulder, a surgical emergency. Associated tears of the rotator cuff are difficult to diagnose during the acute phase but are suspected with displaced tuberosity fractures. Initially, the shoulder should be immobilized in a sling and swathe for patient comfort. Scapular body fractures are rare, usually associated with high energy trauma, and should alert the examining physician to look for associated life-threatening blunt trauma injuries.

Adhesive capsulitis and degenerative arthritis

Adhesive capsulitis and degenerative arthritis can cause concomitant shoulder pain and stiffness in the older athlete. Adhesive capsulitis (frozen

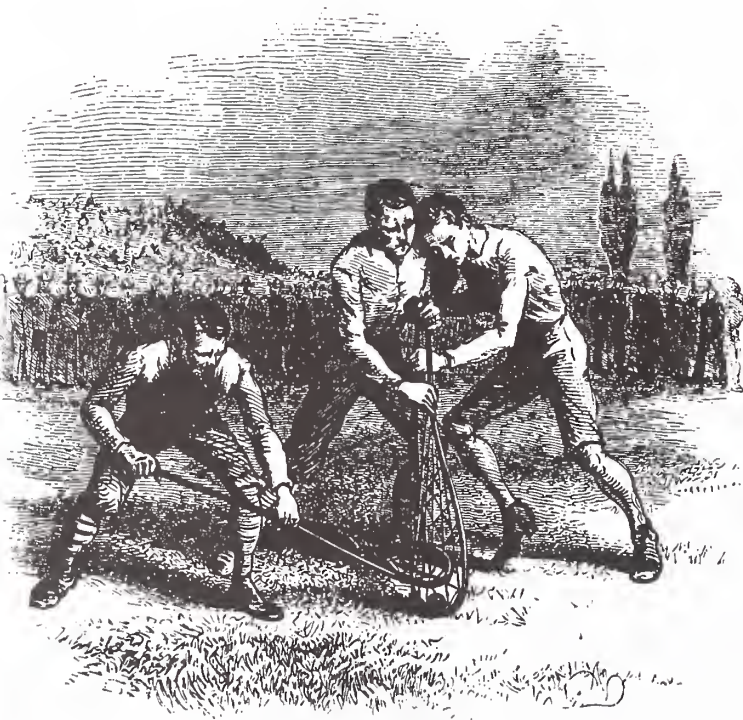
shoulder) is a condition of unknown etiology characterized by significant restriction of both active and passive shoulder motion that occurs in the absence of a known intrinsic shoulder disorder. It typically occurs in females 40-60 years old with an insidious onset of progressive pain and stiffness. By definition, radiographs are normal. The initial painful phase can frequently be disabling and the associated stiffness persists greater than one year. Treatment is geared towards pain control and maintaining shoulder motion as the condition runs its course. Degenerative arthritis of the glenohumeral joint is most prevalent in older patients but may occur at younger ages after traumatic injuries. Progressive wear of the articular cartilage results in the loss of joint smoothness and motion causing symptoms of pain, stiffness and grinding. Radiographs demonstrate loss of joint space, sclerosis and osteophyte formation. Initial treatment is with NSAIDs and a gentle flexibility and strengthening exercises to improve shoulder mechanics. Patients can typically continue to participate in sports despite restrictions of shoulder motion, usually with modifications of technique and diminished endurance.

REHABILITATION

Rehabilitative exercises are the mainstay in the conservative treatment of athletic shoulder problems. The majority of injuries will respond rapidly to a program and not require extensive evaluation. Treatment for shoulder injuries initially is focused on relief of pain using cryotherapy and NSAIDs. Overhead activities are curtailed if pain is affecting athletic performance. Cross-training to maintain cardiovascular fitness is begun immediately for those athletes whose symptoms prohibit normal activity.



Progression into a rehabilitative program of stretching and progressive resistance exercises is dictated by the athlete's ability to move the shoulder without pain. The first phase of shoulder rehabilitation is the re-establishment of normal passive and active range of motion. In particular, loss of internal rotation and horizontal adduction due to posterior capsule contracture are common in overhead athletes with shoulder pain. In general, stretching the anterior capsule with the shoulder in a position of overhead abduction and external rotation is avoided, especially in athletes suspected of having anterior shoulder instability. Strengthening may begin with isotonic exercises within the athlete's pain-free range of motion. The program is advanced to progressive resistance exercises for the rotator cuff and periscapular muscles, using both concentric and eccentric muscle contraction modes. TheraBand (Hygenic, Akron, Ohio) and light weights are used in a step-wise manner, explaining to the athlete the importance of avoiding attempts at rapid progression and excessive use of the shoulder. The muscles of the trunk and lower extremity also play an important role in overhead sports and must be addressed. Return to overhead activity is determined by the athlete's pain and shoulder function. Initial training begins at low intensity levels, usually under the direction of a trainer or coach, progressing as symptoms tolerate. A set daily schedule of number and intensity of exercises may be necessary to avoid overzealous training and recurrence of symptoms in the early stages of returning to overhead activities. If the athlete has an exacerbation of symptoms during rehabilitation or return to sports, the program is restarted at the appropriate level. Failure to respond to an organized rehabilitation program over a 3-6 month period may warrant further evaluation and possible surgical intervention.



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Sports-Related Ocular Injuries

Joseph F. Ducharme, MD, and William G. Tsiaras, MD

The eye and orbital tissues are susceptible to a variety of injuries from trauma. An estimated 2.4 million ocular injuries occur annually in the US, of which approximately 100,000 are sports related.¹ Children and young adults are especially vulnerable. In the sixteen and under age group, sports and recreational activities accounted for approximately 27% of all eye injuries, only slightly below accidental blows and falls (37%). In the eleven to fifteen age group, sports and recreational activities account for the majority of pediatric ocular trauma.²

Among both adults and children, there is a much higher incidence of male to female injuries (approximately 3-4:1 ratio). In the five to 14 year-old-age group,⁵ baseball is the most common cause of eye injuries followed by pool and swimming sports. In adults, basketball accounts for the most injuries (28.9%) in both the 15 to 24 year-old-age group, and (19.0%) in the 25 to 64 year-old-age group. Racquet sports are the next most common cause of injuries in adults. Overall, basketball accounts for more injuries than any individual sport (17.2%).³

In sports, eye injuries can occur from direct contact with other competitors, projectiles, and equipment. Although most injuries do not cause long-term debilitation or vision loss, a significant number of preventable injuries lead to persistent ocular morbidity and blindness. This paper presents a few of those more common ocular injuries. Additionally, a discussion of appropriate prevention and protection against ocular and orbital injuries in general will be included.

I-Anatomy

Structures to be discussed in this article include the orbit and adnexal tissues as well as all the structures of the eye including the optic nerve. (Figures 1, 2, 3.)

II-Eye and Orbital Injuries

Several different types of eye and orbital injuries can occur as a result of

trauma. More importantly, injury to one structure, if severe enough, can be accompanied by injuries to other structures around the eye and the eye itself. Careful attention to the patient's history, symptoms and signs will alert one to the nature of the problem. Frequently, nonphysicians, and more specifically, physicians unaccustomed to examining the eye may have difficulty determining the extent of an injury. In those settings, the caregiver should consult with a physician trained in dealing with ocular injuries. The following list describes some of the more common traumatic injuries, to help alert the non-ophthalmologist to potential injuries.

1-Eyelid Lacerations

The skin around the eye and orbit, the thinnest skin of the body, provides the initial barrier to contact. Trauma to this area can cause skin and eyelid lacerations. The two important types of eyelid lacerations which require more thorough evaluation include full-thickness eyelid lacerations and eyelid margin lacerations.

Eyelid margin lacerations of the upper or lower eyelids require special type of care. Without proper suturing, the eyelid may not only have a poor cosmetic appearance but may have a poor functional result. Malposition of the eyelid margin may lead to chronic corneal irritation. Additionally, any eyelid margin laceration which involves the medial one-third of the eyelid may involve the tear drainage system (see Figure 4). The tears are usually gathered through two small punctae which lie medially on the inner aspect of both the upper and lower eyelids. These punctae drain to small canaliculi which lay at the nasal eyelid margin of both upper and lower eyelids and connect to a lacrimal sac in the nasal aspect of the orbit. This lacrimal sac eventually empties via the nasolacrimal canal beneath the inferior meatus inside the nose. Eyelid lacerations that pass through the

Abbreviations Used:

ANSI	American National Standards Institute
ASTM	American Standard of Testing Materials
CSA	Canadian Standards Association

canaliculus will sever connections to the nasolacrimal system. Repairs in this area which do not reattach the canaliculi may result in chronic tearing and ultimately chronic corneal problems. Repairs in this area are usually done via a microsurgical technique involving a silicone stent which is left in place for a period of weeks to months until the system has fully healed.

Eyelid lacerations above the eyelid margin also require specific attention. Commonly, after a severe laceration, the eyelids are markedly edematous. These eyelid lacerations need to be carefully opened and inspected since a penetrating globe injury is possible (Figure 12). Also, any laceration full-thickness through the eyelid margin may interrupt the levator muscle or the levator aponeurosis. Improper identification of this type of injury will lead to upper eyelid ptosis. Ways to identify this type of injury prior to suturing include everting the eyelid to look for a full-thickness penetration and identification of fat protrusion through the wound. Deep lacerations that penetrate through the orbital septum often liberate orbital fat. Just beneath the orbital fat is the levator muscle and tendon. Thus, orbital fat protrusion is a sign that the wound needs to be more thoroughly investigated.

Both injuries are often associated with damage to contiguous ocular structures either from blunt contact or direct penetration. Thus, it is essential that the globe be thoroughly evaluated prior to any suturing.

2-Orbital Fracture

The orbital bones support the globe and also provide housing and a conduit for the cranial nerves and blood vessels

that enter through the posterior orbit. The orbit also contains the lacrimal gland which is in the superotemporal quadrant. Lastly, the six periocular muscles have their origins from the periosteum of the orbital bones both at the posterior and anterior orbital tissue.

The orbit itself is described as an “inverted pear”. The orbital structures are often divided anatomically and functionally into: roof, medial wall, floor, and lateral wall. Objects larger than the globe often strike the orbital bones initially. Fractures of these tissues can have different presentations and means of treatment. Damage to the orbital bones can occur as a result of direct trauma or indirect trauma to adjacent bones. An orbital CT scan with axial and coronal views is the best way to image the orbital bones.

Orbital roof fractures, although not common, are an indication for immediate surgery since communication with the brain contents can occur via disruptions of the frontal sinus. Although the lateral wall of the orbit is the strongest of all the walls of the orbit, it is often most susceptible to trauma. Fractures of this area often involve the zygomatic arch. These types of fractures, known as tripod or trimalar fractures, are often repaired for cosmetic purposes. Specific signs of a lateral wall fracture include a depression of the cheek bone area, as well as difficulty with jaw opening due to disruption of the temporo-mandibular joint. Damage to the medial orbital wall, which is the thinnest of all the orbital walls, usually occurs indirectly from damage to the orbital floor.

A more common orbital fracture is fracture to the orbital floor. Damage to the orbital floor can result in three specific problems (Figure 5). First, if a significant portion of the orbital floor, which supports the globe and periocular tissues, is destroyed, there is a potential for *enophthalmos*, where the eye and orbit structures actually sink through the floor into the maxillary sinus. *Enophthalmos* may not be evident for weeks to months after the initial trauma due to orbital edema and hematoma. Most oculoplastic surgeons feel that damage to more than 50% of the orbital floor will eventually result in this complication and

thus repairs are made for large orbital floor fractures. With smaller orbital floor fractures, some of the periocular tissues inferiorly (including connective tissues and muscle) can be trapped due to negative pressure in the maxillary sinus. This condition may cause a restrictive motility disorder and can result in double vision. Double vision itself after orbital trauma may result from several different possibilities. Among these include cranial nerve damage from direct head injury, localized edema and hematoma limiting movement of muscle, and local nerve or muscle damage caused by trauma. Many of these entities can be ruled out by an ophthalmologist. Since a restrictive disorder will often give persistent diplopia, this is another indication for orbital floor repair.

A last indication for surgery is when the anterior maxillary wall is crushed, creating a cosmetic defect.

An interesting type of orbital floor fracture can occur without direct fracture to the anterior maxillary wall or orbital rim. This is often termed an *orbital blowout fracture*, where an object larger than the orbit strikes the orbit in such a way that the orbital floor buckles and is fractured indirectly. Some specific signs of orbital floor fractures, other than *enophthalmos* and diplopia, include crepitance (air in the subcutaneous tissues from the periorbital sinuses), and paresthesias over the midfacial skin or upper teeth (indicating a disruption of the maxillary nerve as it crosses over the orbital floor).

After an orbital fracture has been diagnosed, an oral antibiotic is recommended for prophylaxis, since bacterial flora from disrupted sinuses have access to orbital tissues. The patient is also instructed not to blow his/her nose for a period of time as not to raise the pressure in the periorbital sinuses. Certainly after any orbital injury, protective eye wear should be used in any contact situation. These types of eye wear will be discussed below.

3-Conjunctival Hemorrhage/Laceration

Both blunt and penetrating injuries can often affect the conjunctiva, the delicate mucous-secreting membrane that

covers the anterior portion of the eye and the under surface of the eyelids. Conjunctiva stops at the limbus, which is defined by the transition area between the sclera and cornea. Note that the conjunctiva does not cover the cornea. The conjunctival tissue, besides containing mucous-secreting goblet cells, has blood vessels in a very thin interstitial space. Minor trauma to this tissue with disruption of the vessels can cause a marked area of subconjunctival bleeding, since there is little resistance to the spread of the subconjunctival blood (Figure 6).

Minor subconjunctival hemorrhages are quite common with even minor trauma, and even occur after a forceful Valsalva-type maneuver. With more serious injury, the conjunctiva can be torn creating bleeding which is quite obvious coming from the eye itself. Most subconjunctival hemorrhages cause minimal symptoms, unless the hemorrhage and edema is large enough to keep the eyelids open. This exposure phenomena can cause corneal irritation and drying. Topical lubricants and occasional pressure patches, as well as time, will help resolve this condition. Most conjunctival lacerations rarely require suturing. These often heal quite quickly and often a topical antibiotic prophylaxis is placed to prevent infection.

More importantly when a conjunctival hemorrhage is seen after direct impact to the eye, the eye itself should be assessed for undetected injury, especially if visual symptoms or obvious associated injuries such as hyphema (see section 5) are seen. Due to its delicate nature, the conjunctiva is not an effective barrier to the eye from trauma. In one study, 16% of the patients who presented with subconjunctival hemorrhage had micro hyphemas or hyphemas. Also 23% of these patients with subconjunctival hemorrhages had posterior segment hemorrhages or commotio retinae.⁴ Once a subconjunctival hemorrhage is detected after trauma, this should be a definite sign that the eye is at risk for further injury which must be assessed by a specialist.

4-Corneal Abrasion

The cornea is a clear, transparent dome-like structure which provides the majority of the refractive power of the

eye. It remains clear due to its lack of blood vessels, its regularly arranged collagen fibrils of the same periodicity, and its relative deturgescence. The corneal endothelium is crucial as it acts like a pump, passing water back into the anterior chamber across a concentration gradient.

Corneal abrasions are among the most common injuries after sports-related trauma. Larrison et al found that approximately 35% of hospital emergency room presentations after sports-related injuries involved corneal abrasions.⁴

In direct trauma to the cornea surface, the epithelium can be abraded, exposing a richly sensory innervated tissue. The resulting symptoms depend on the area abraded and its location. Small abrasions tend to have symptoms of a foreign body-type sensation, where the affected person complains of "grittiness, scratchiness," or "hair in the eye." Larger abrasions can cause extreme pain, blurred vision, and tearing (in reflex to the sensory nerve stimulation). This pain can be quite severe and debilitating. Often the affected person cannot open the eyelid. Vision is blurred from central abrasions and from copious tearing.

Fortunately, superficial abrasions heal quite quickly, often with re-epithelization occurring between one to three days from the insult. Treatment at the initial stages includes pain control mainly. Many affected people require oral narcotic agents for pain control for a short time. Often a pressure patch is applied to the eyelid to keep the eyelid closed. The pressure patch is not a therapeutic aid; rather the closed eyelid gives much more comfort.

Often a topical antibiotic in the form of an eyedrop or ointment is added as a prophylaxis from corneal infection. As the epithelium heals, the vision and symptoms gradually return to normal. Occasionally, a deeper abrasion causes disruption of the corneal stroma. The resulting repair may result in scar formation from non regular areas of collagen formation. Corneal scarring can lead to poor vision and glare symptoms.

As with subconjunctival hemorrhages, corneal abrasions may be associated with more important ocular injuries.

In a study by Larrison, of the 70 patients who presented with corneal abrasions, 12 (17%) had posterior segment hemorrhages or commotio retinae. They suggest that 8-26% of patients presenting with corneal abrasion sustained by a sports-related activity can expect to have posterior segment trauma. Also, 16% (11 of 70) patients presenting with corneal abrasions from sports-related injuries sustained microhyphema or hyphema. This emphasizes the need for an ophthalmic examination after even a "minor" injury.⁴

Diagnosis of corneal abrasion is often made by the type of symptoms and the type of injury. An abrasion is easily highlighted after applying topical fluorescein and viewing the eye with a cobalt blue filter (Figure 7).

One additional situation where a traumatic corneal abrasion becomes more complicated is in the setting of contact lens wear. Patients who are chronic contact lens wearers will be more prone to both corneal abrasions and to corneal infections with gram negative organisms. Some physicians recommend not patching abrasions in a contact lens patient and prophylaxing these patients with topical agents that are effective against gram negative organisms (i.e.; gentamycin, tobramycin, fluoroquinolones), continuing until the epithelial defect is repaired.

5-Hyphema

Blunt injury to the eye may cause bleeding in the anterior segment of the eye. Usually, the site of bleeding in a traumatic hyphema is from the vascular ciliary body or iris base where the major vascular arcades of the anterior segment of the eye reside. Hyphemas can be either microscopic, only seen in slit-lamp examination, or macroscopic, where blood is grossly seen layering at various heights in the anterior segment of the eye (Figure 8). Vision is variably affected, depending on how much blood is obscuring the visual axis. Also, inflammation in the ciliary body or iris can lead to pain, headache, and photophobia.

Traumatic hyphemas signal a serious injury to the anterior part of the eye. Blood will eventually pass out of the eye via the normal aqueous passageways

through the trabecular meshwork, Schlemm's canal and back into the venous system. As the blood drains, however, the intraocular pressure may rise as a result of blood clogging the aqueous pathways. Usually, the intraocular pressure rise is transient. Special circumstance where this is important is in patients susceptible to sickle cell disease. Not only do patients with sickle cell disease have the tendency for blood to sickle in the trabecular meshwork, their optic nerves cannot tolerate even mild elevations in intraocular pressure. Thus, even slight rises in intraocular pressure in these patients may often necessitate surgical drainage of the blood. Patients who develop hyphemas and who are at risk should be screened for sickle cell disease initially.

Traumatic hyphema has additional risks to the eye. Blood and inflammatory cells in the anterior chamber of the eye can eventually precipitate a cataract, often occurring years after the initial injury. Injury to the iris and ciliary body can further cause a permanent functional disruption of the drainage structures in the eye leading to a condition known as *angle recession*. This condition can lead to permanent intraocular pressure elevation and glaucomatous optic nerve damage, early or potentially years after the initial injury. Traumatic eye injuries producing hyphemas often involve adjacent structures as well. Retinal injury (retinal tear, retinal detachment, retinal dialysis, and choroidal rupture) can occur in the setting of an injury that causes a traumatic hyphema.

Patients who have suffered a traumatic hyphema should remain under strict activity limitations for the first five days. During this period, the risk for rebleeding is at its highest. Rebleeding often bodes for a poor prognosis in terms of final visual acuity and intraocular pressure. After a period of bed rest, during which the patient is closely monitored, the return to activity is often gradually increased. When patients return to full activity, polycarbonate lens protection, especially during athletics, should be instituted. Also, routine ophthalmic examinations for glaucoma, cataract and retinal problems should be made.

Children with traumatic hyphemas deserve special attention. Since children often cannot follow instruction of limited activity and bedrest, careful consideration should be made to the family's status and siblings to estimate whether bed rest is likely. Often, children are admitted to the hospital to insure compliance. In prior years, many eye centers admitted all hyphemas, but this has become less the trend in recent years.

6-Traumatic Lens Injury

The lens, which is attached via hair-like zonules to the ciliary body, is frequently affected with blunt trauma to the anterior segment. These zonules can be torn causing the lens to either become slightly out of position (subluxation), or completely displaced from position (dislocation). This type of injury often occurs in the setting of patients who may have a pre-disposition to have weak zonules (high myopia, Marfan's syndrome, or other inherited conditions). Subluxation of the lens may only be evident after the patient's pupil is dilated. The patient may or may not have visual symptoms at this point, but subluxation can lead to future cataract formation. Dislocation of the lens, however, may lead to immediate vision loss since the lens is responsible for approximately one-third of the focusing power of the eye. Through a dilated pupil a dislocated lens can often be seen in the posterior vitreous cavity.

In general, damage to the lens is painless since the lens is not sensory innervated. Dislocation or subluxation of the lens anteriorly may cause a blockage of aqueous flow through the pupil and a marked elevation of the intraocular pressure (pupillary block glaucoma). Immediate symptoms of this include intense pain, headache, nausea, vomiting, blurred vision, and a fixed pupil. This is an emergency and demands immediate ophthalmic attention.

Any injury to the eye especially involving blood or inflammation, can cause cataract formation. Cataract can occur days to years after the initial insult. A unilateral cataract in a young person is often the result of a traumatic injury in the past.

7-Traumatic Retinal Injury

Blunt trauma to the eye can cause retinal injuries. Occasionally these injuries are fleeting, but sometimes they can cause permanent visual loss. In general, retinal injuries do not cause pain since the retina is not innervated by sensory fibers.

One of the more common retinal injuries that can lead to blurred vision is a condition called *commotio retinae* (Figure 9). This is a disruption, fortunately temporarily, of certain structures in the retina. This is seen on ophthalmic examination as a whitened area in the retina. If this were to involve the central part of the vision near the fovea, the patient may complain of blurred vision. If it is located in the periphery of the retina, it is often asymptomatic. Fortunately this condition resolves almost completely.

*In most high risk sports,
the majority of serious eye
and orbital injuries can
be eliminated with
proper protection.*



Another type of retinal injury is a hole or dissociation of the retina from its anterior attachment at the retinal base (retinal dialysis). These occur from sudden shifting of the vitreous gel attached to the retina at the periphery. Sudden shifting of the vitreous by coup or countercoup forces can lead to tearing of adjacent retinal tissue. Again, retinal tears are not painful. They may be asymptomatic or may cause *floaters* where blood and/or retinal tissue is liberated in the vitreous cavity after being torn. Also, a retinal tear can cause sensation of flashes of light, where continued traction of the vitreous against a torn piece of retina stimulates a "lightning-type" event.

Retinal tears in a traumatic setting are often at the far periphery of the retina and must be seen by a trained ophthalmic person after the pupil is dilated. Often retinal tears or retinal dialysis can lead to fluid entering in between the retina and the subretinal tissues causing a retinal detachment (Figure 10). Symptoms of

retinal detachment depend on the area involved; peripheral detachments can be asymptomatic initially. Whereas retinal tears can often be treated with in-office laser therapy or cryotherapy, retinal detachments often require surgical intervention. Again, retinal detachments may occur several weeks to years after a traumatic injury. A high suspicion of retinal damage based on the type of injury, as well as frequent examinations years after the original injury, can help with early detection of a potentially visual-threatening detachment.

Another condition which can cause permanent visual loss is a choroidal rupture (Figure 11). Usually, sudden compression of the eye from blunt trauma may lead to a sheering force in the choroid which disrupts the overlying retina. These affected areas appear concentric to the optic nerve and often pass through the fovea. Unfortunately, this can lead to permanent visual loss if the rupture disrupts the fovea. Also, the injury that causes a choroidal rupture often requires a force that will cause associated injuries such as a traumatic hyphema or a traumatic retinal problem.

8-Ruptured Globe

One of the more feared and disastrous complications of both blunt and penetrating trauma of the eye is rupture of the globe. After blunt trauma, the globe will rupture at its weaker areas; at the limbus (the junction of the sclera and cornea) and posterior to the ocular muscles. The globe is also weakened at sites of prior incisional surgery such as cataract surgery, radial keratotomies, or corneal transplant. Penetrating eye injuries from sharp objects can lacerate any portions of the globe. Sharp injuries through the eyelids, as mentioned previously, can also penetrate through the globe (Figure 12). Specific symptoms of a globe rupture include sudden vision loss and marked eye pain. Signs include disruption or extrusion of the ocular contents, bleeding, large hyphema, and hypotony.

Prompt attention is paramount. Often multiple surgical interventions are required to restore vision. The most immediate concern after this injury is infection, which could lead to loss of the

eye itself. When a globe rupture occurs, a barrier shield should be placed over the eye with minimal pressure as possible as not to extrude intraocular contents. The patient is immediately referred to an ophthalmologist for surgical intervention. On certain occasions, a globe rupture can be subtle and only picked up by careful examination.

III-Eye Injury Prevention

In most high-risk sports, the majority of serious eye and orbital injuries can be eliminated with proper protection. Unfortunately, while many amateur sports have mandated protection for younger athletes, many other sports including professional sports have not done so. Children, overall, appear to be most at risk for eye injuries; 71% of the 41,000 sports related and recreational eye injuries treated in hospital emergency departments in 1993 occurred in children younger than 25 years. Both the NCAA and the AAO commission have set forth recent recommendations for athletes participating in sports.^{5,6}

Two sports which have made great strides in mandating eye and orbital protection, resulting in a dramatic reduction in eye injuries, are amateur ice hockey and racquet sports. A 1977 review of professional hockey players found that 60% had suffered eye or facial injuries by the time they were in high school. Virtually 94% of this group had suffered either facial fractures, scars, missing teeth or an eye injury. Important steps taken to prevent this were initially instituted in Canada. The Canadian Amateur Hockey Association initiated requirements of the Canadian Standard Association (CSA) Z262.2. This required eye protectors for ice hockey with a small aperture wire mask for all players. In July 1976, the Amateur Hockey Association of the United States mandated facial protection for its 260,000 players at that time. Based on this 1981 study, approximately 70,000 injuries were prevented each year, resulting in an estimated \$10,000,000 in savings each year. Unfortunately, despite the marked reduction in ice hockey injuries, professional players are not required to wear eye or facial protection. Thus, the incidence of ocu-

lar and facial injuries is much higher in this group.⁷

In racket sports, especially racquetball, the ball, which is small and travels at high speeds, is funneled past the orbit directly to the globe. This often results in devastating injuries and vision-threatening problems. In 1983 the American Standard of Testing Materials (ASTM) passed a standard F803 for racket sports. This was later updated several times. Concurrently, the Canadian Standards Association (CSA) drafted a preliminary standard Z400-m which is also revised for racket sports. Both standards are performance rather than design standards. That is, eye guards which pass these standards will prevent contact by a racquetball or squash ball at speeds of 90 miles per hour when impacted from the front or the side. Optical quality and field of vision standards were also specified. Open-type protectors were disallowed.⁸

In general, most of these eye protectors are designed such that the orbit and the bones around the face absorb the shock from an injury.

In the United States, ASTM does not certify protectors but only sets standards. Protectors can be made with or without prescription polycarbonate material or can be made to cover prescription glasses. Any of these structures that meet the standards of the ASTM are acceptable. As of 1988, approximately five years after the standards were introduced, no significant eye injury had been reported in a squash or racket player wearing either CSA or ASTM approved eyeguards.⁸

Corrective lenses in glasses do not meet standards. In high-risk sports, ASTM standards should be the rule. Industrial spectacles and goggles should meet the American National Standards Institute (ANSI) standard Z81.1 with polycarbonate or CR39 lenses. The lenses for sports goggles (Figure 13), however, should be made of at least 3 mm of polycarbonate, which is stronger than the CR39 material. Most prescriptions can be ground into a polycarbonate-type lens. Unfortunately, certain high refractive errors cannot use polycarbonate lenses. To remedy this, either glasses covered by clear appropriate shields or contact lenses

followed by sports goggles with clear polycarbonate lenses should be used. It should be emphasized that contact lenses do not protect against trauma. Although providing many athletes with a crisper vision and a better peripheral visual field, corrective lenses cannot take the place of safety goggles in sports activities. Also since contact lenses may be dislodged or become uncomfortable, sports trainers should have appropriate contact lens solutions and replacement lenses available.⁵

Another question is *Who should wear protective eye wear?* Two conditions where eye protection should be mandated are in functional one-eyed patients where the second eye has either lost vision or has poor vision, or in patients who have had prior ocular trauma. Of note, prior trauma also includes previous eye surgery. Surgeries such as radial keratotomy will weaken the eye making it more vulnerable to rupture during blunt trauma. These two groups of people should not participate in high-risk sports, such as martial arts, boxing, and wrestling, where eye protection is not practical.

XII-Conclusion

Ocular and orbital injuries are a common result of participation in sports. Both proper protection in high-risk sports and recognition of participants with high-risk eye conditions could markedly reduce traumatic injuries and ocular morbidity. Prompt evaluation by an ophthalmologist even after minor trauma should be the take-home message of the paper.

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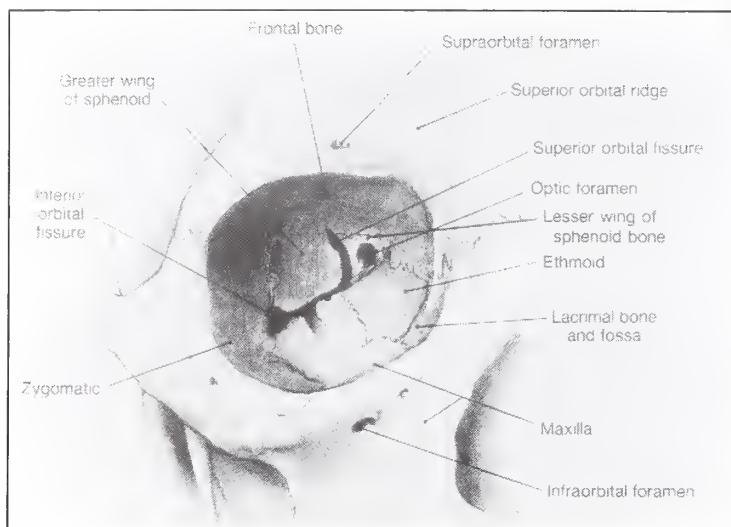


Figure 1: Anatomy of the bony orbit.

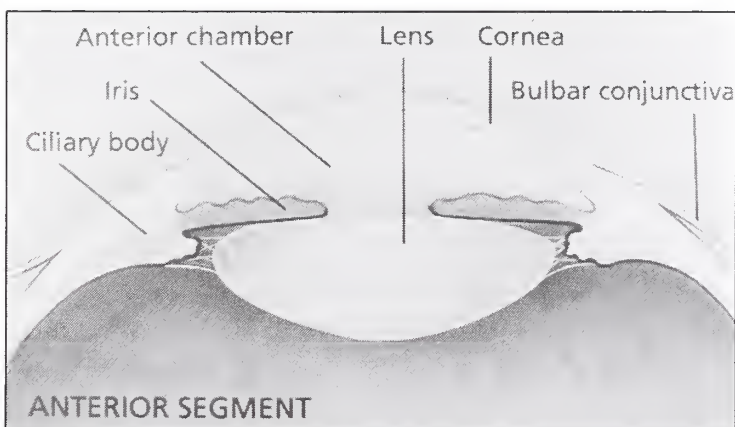


Figure 2: Anterior eye anatomy.

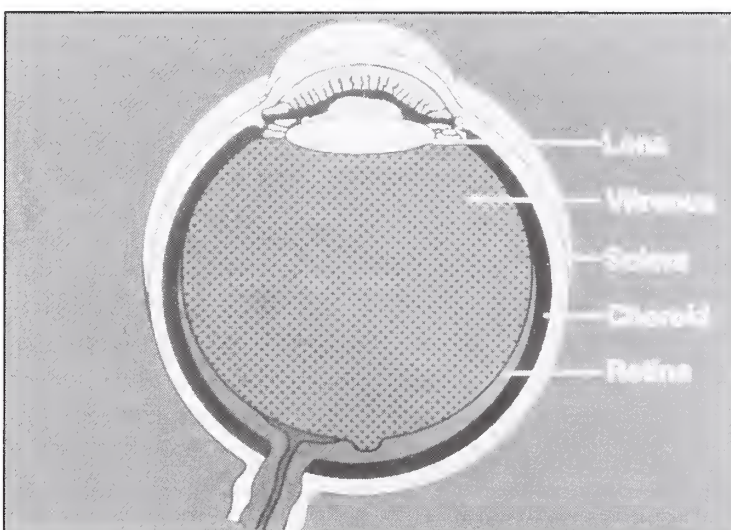


Figure 3: Posterior eye anatomy.

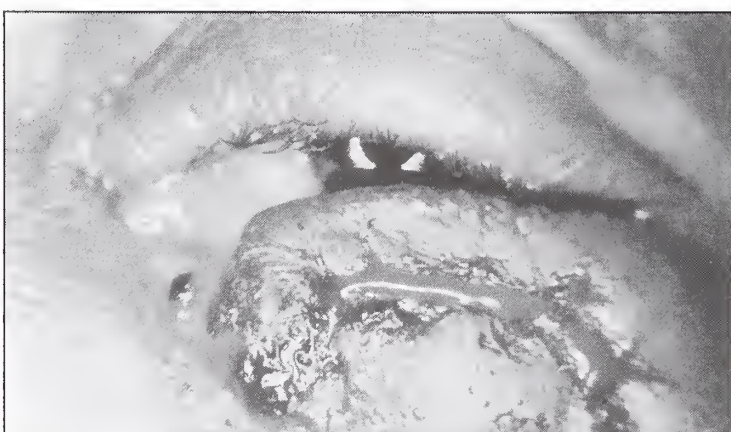


Figure 4: Full-thickness eyelid laceration of the nasal aspect of the left lower eyelid, involving the canalicular portion of the tear drainage system.



Figure 5: Enophthalmos and restricted upgaze of the right eye following a right orbital floor fracture.

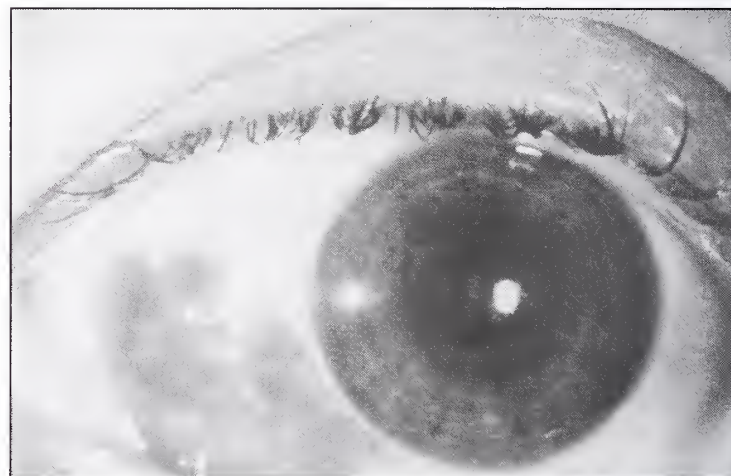


Figure 6. Subconjunctival hemorrhage.

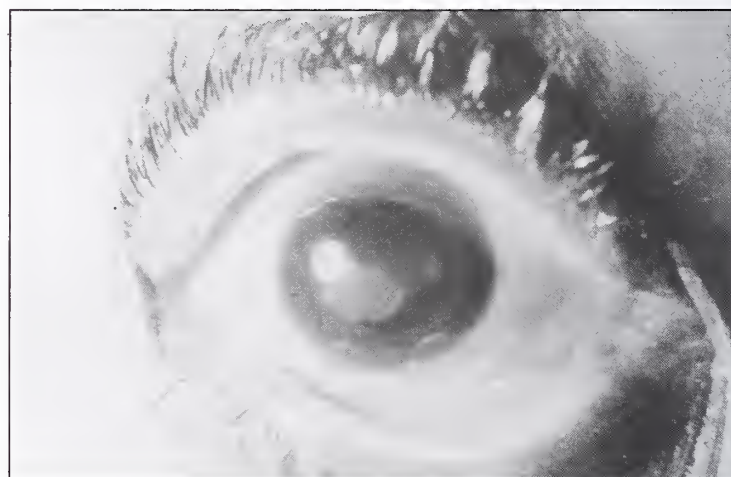


Figure 7. Corneal abrasion, the epithelial defect, highlighted by topical fluorescein, would illuminate bright green under a cobalt blue filter.

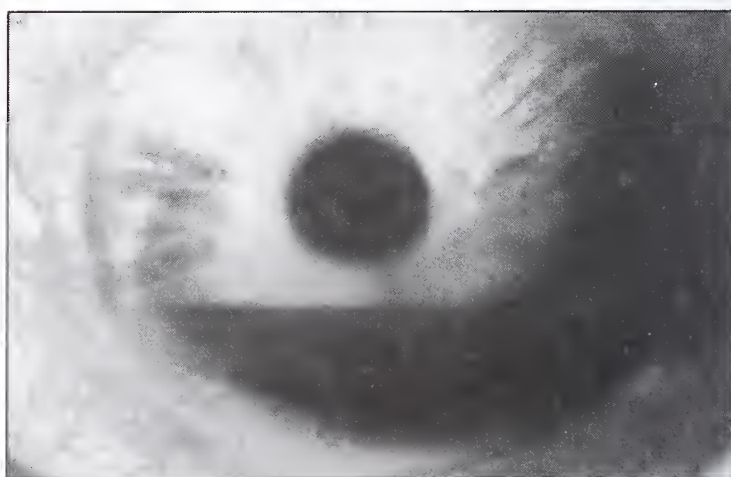


Figure 8. Hyphema, blood is layering in the anterior chamber inferiorly.

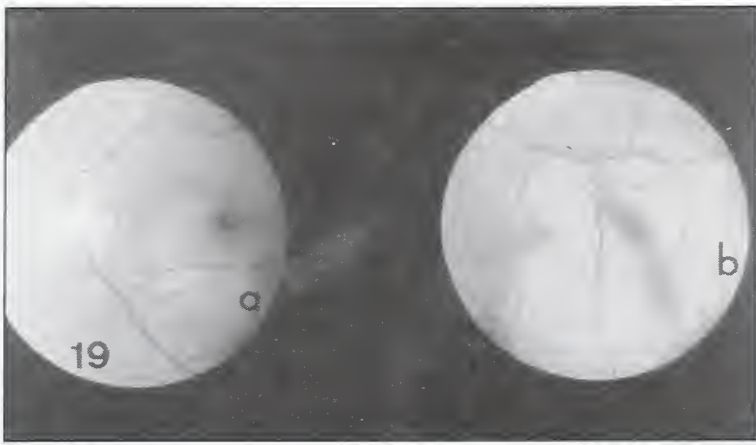


Figure 9. Comotio retinae, the affected areas in a and b appear whitened.



Figure 10. Large retinal tear with retinal detachment.



Figure 11. Choroidal rupture- semicircular areas of scarring through the fovea of the right eye. The dark area temporal to the optic nerve is intraretinal hemorrhage.

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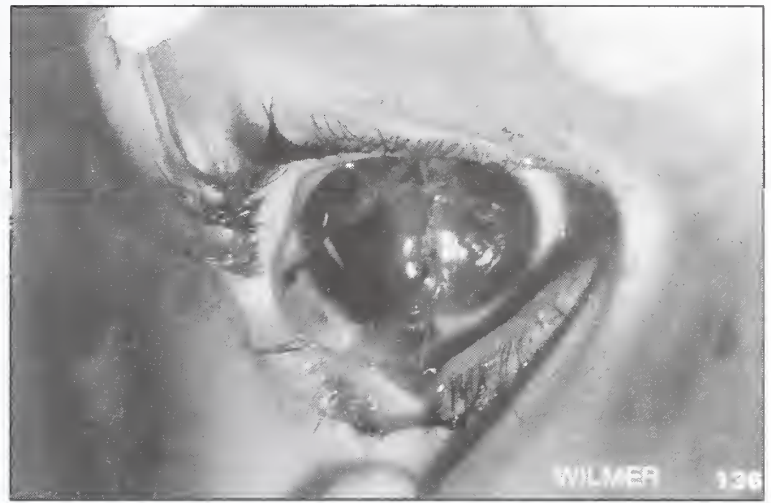


Figure 12. Ruptured globe with hemorrhagic prolapse of intraocular contents. Note the full-thickness lower eyelid laceration. (Photo courtesy of Johns Hopkins Hospital, Eye Trauma Center, Wilmer Institute ©1984).

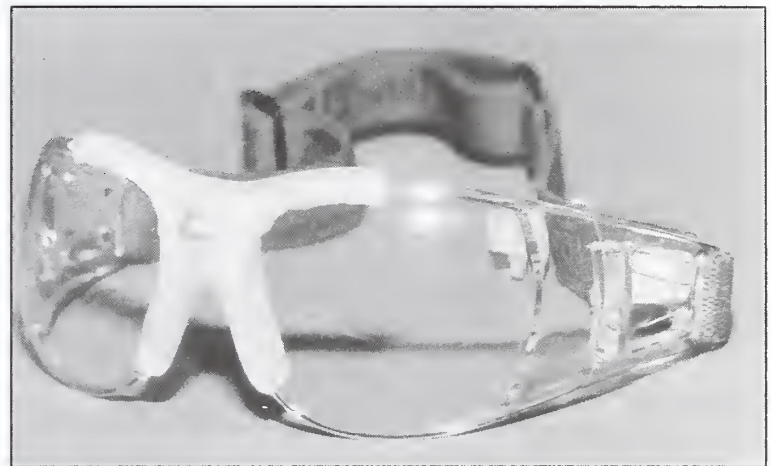


Figure 13. Example of protective eye wear for sports.

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Exercise-Induced Asthma

Vera A. DePalo, MD, and F. Dennis McCool, MD

Asthma is a pulmonary condition characterized by inflammation, airway narrowing, and reversible airflow limitation. Exercise is just one of many stimuli which can trigger asthma and limit airflow. Exercise-induced asthma can be defined as an acute, reversible, episode of airway obstruction that occurs during or up to 30 minutes following physical activity. It is characterized by acute airway narrowing or bronchospasm in individuals with increased airway reactivity.

CLINICAL FEATURES

As many as 80% of patients with asthma and 40% of patients with allergic rhinitis wheeze or have a decrease in expiratory flow rates of at least 10% with exercise.¹ It can be seen in normal first-degree relatives of patients with asthma and in patients with atopic allergy who do not have asthma.² While exercise-induced asthma can be seen at any age, it is most often seen in children and young adults because of their higher levels of physical activity. Exercise-induced cough or wheeze can be the first manifestation of asthma in children or active adults.³

The degree of bronchospasm induced by exercise depends upon the degree of underlying airway inflammation, the intensity and duration of exercise, and the physical characteristics of the ambient air. Short episodic exercise produces few problems. As the intensity and duration of exercise increases, symptoms will more likely occur. Accordingly, running produces more airflow limitation than walking. Exercise-induced bronchospasm is further enhanced by breathing cold, dry air. When exercise ends, individuals can feel symptoms indistinguishable from those noted during an asthma attack; namely, wheezing, cough, shortness of breath, dyspnea, and chest tightness. Sometimes exercise-induced cough may be the sole complaint.

AIRWAY MECHANICS AND EXERCISE

With increased exertion, the frequency of breathing and the volume of

air inhaled increases to meet the oxygen demands of the contracting muscles and to maintain acid base homeostasis. With maximal exercise, ventilation may be more than 30-40 times that needed at rest. The large volumes of air that are inhaled with exercise are moved at high flow rates and gas velocities; both factors increase airways' resistance. To lessen this increase in resistance, normally the airways dilate. This increase in airway caliber is thought to be due to breathing at higher lung volumes and to release of endogenous epinephrine that effects airway smooth muscle tone. By contrast, individuals with exercise-induced asthma typically experience airway narrowing rather than dilation after 5-10 minutes of exercise. With continued exercise, airflow limitation may progress, reaching a nadir in 5 to 10 minutes. In some individuals, airway obstruction improves with continued exercise and may spontaneously resolve in about 30 minutes. Subsequently, a refractory period during which further exercise causes no bronchospasm may last up to 30-90 minutes. This refractory period may occur in as many as 50% of individuals with exercise-induced asthma. However, in others, continued exercise leads to further reductions in expiratory flow rates. In as many as 25% of individuals with exercise-induced asthma, a later phase of bronchoconstriction may recur as long as 3-8 hours after exercise has been completed. This late phase response may be related to circadian fluctuation of bronchodilator tone and cannot be predicted by gender, asthma severity or atopic status.⁴ The changes in airway mechanics that typically occur in individuals with exercise-induced bronchospasm are shown in the Figure. Exercise-induced changes in airflow limitation may also adversely affect the inspiratory muscles. Exercise-induced bronchospasm imposes a resistive load on the inspiratory muscles. Such resistive loads increase the work and oxygen cost of breathing thereby further increasing CO₂ production and the need for ventilation.⁵ In addition, as airflow limitation progresses, these individuals

Abbreviations Used:

FVC	forced vital capacity
FEV ₁	forced expired volume in 1 second

are forced to breathe at higher lung volumes. With hyperinflation, the efficiency of breathing decreases. This further increases the oxygen cost of breathing. Thus individuals with exercise-induced asthma may partake in physical activity, but incur higher ventilatory costs for a given degree of activity.⁶

PATHOGENESIS

The pathogenesis is closely linked to the warming and humidification of the large volumes of air which are drawn into the tracheobronchial tree during exercise.^{7,8} Normally, inhaled air is warmed to body temperature and fully humidified by the time it reaches the lower airways (water vapor pressure of 40 cm H₂O at 37° C). This process involves fluxes in heat and water across the mucosa. The mucosa of the nose, mouth and pharynx participate to the greatest degree in this warming and humidification process. The mucosa of the tracheobronchial tree participate to a lesser degree.

To better accommodate the large volumes of air that rapidly enter the respiratory system, individuals will breathe through the mouth, thereby bypassing the nose. This strategy places a greater burden for humidification on the tracheobronchial tree.^{8,9} Under these circumstances, the capacity of the upper airways to warm and humidify inhaled air may be overwhelmed. Consequently, airway temperature falls. Greater fluxes in heat and water across the tracheobronchial mucosa are needed to warm and humidify the inspired air. Such fluxes will trigger bronchospasm with the magnitude of induced bronchoconstriction depending on the level of ventilation, the heat and water content of the inspired air, and the efficiency of the warming and humidification process or thermal equivalent. With lower ventilatory vol-

umes of warmer and more humidified air, the magnitude of the thermal and water fluxes across the mucosa are diminished and the potential to induce bronchoconstricting is reduced.

It has been postulated that thermal and water fluxes cause bronchoconstriction through their effects on histamine release.⁶ With this mechanism, the airway cooling that occurs with hyperpnea may lead to water loss from the tracheo bronchial mucosa. This, in turn, causes respiratory tract hyper osmolality which may lead to mast cell degranulation, histamine release, and consequent bronchoconstriction.¹⁰ However, it has been argued that the changes in airway osmolality due to exercise-induced hyperpnea are insufficient to trigger mediator release.⁷

Another hypothesis linking thermal fluxes to bronchospasm focuses on the finding that asthmatics have a hyperplastic tracheo bronchial capillary bed which may be more permeable than usual. The thermal flux associated with exercise hyperpnea may cause a sudden increase in local blood flow and further changes in vascular permeability in asthmatics. These changes may result in a greater influx in inflammatory cells and subsequent cytokine release. Thermal fluxes may also occur following exercise. In this context, the inspired air is warmer and more humidified by the time it reaches the lower airways. Thus when ventilation is suddenly reduced, a rapid warming, rather than cooling, of the tracheo bronchial mucosa occurs. This also may lead

to more rapid rewarming of the airways and hyperemia with subsequent airway edema and narrowing.¹¹

Whether the factor initiating bronchoconstriction is a change in airway osmolality or hyperemia, it is likely that neutrophil chemotactic factors and leukotrienes are important mediators. The observations that increases in levels of these molecules coincide with the development of airway obstruction and that pretreatment with leukotriene 4 receptor antagonists can prevent exercise-induced bronchospasm suggest that there is a role for the 5 lipoxygenase pathway in the pathogenesis of exercise-induced bronchospasm.

DIAGNOSIS

The diagnosis of exercise-induced bronchospasm rests heavily on the history. Important areas to explore include the types and levels of exercise that cause bronchospasm, how the reaction develops, conditions that modify the hyperreactive response, and how it resolves. One should seek a history of wheezing, coughing, or chest tightness during or after exercise. Some individuals will state that they only have difficulty breathing during vigorous activity. These complaints are often attributed to lack of conditioning. However, if someone chooses to be sedentary, they may do so because of the discomfort associated with exercise-induced bronchospasm. In this context, a high level of suspicion is often needed to make the diagnosis of exercise-induced asthma. There should also be a

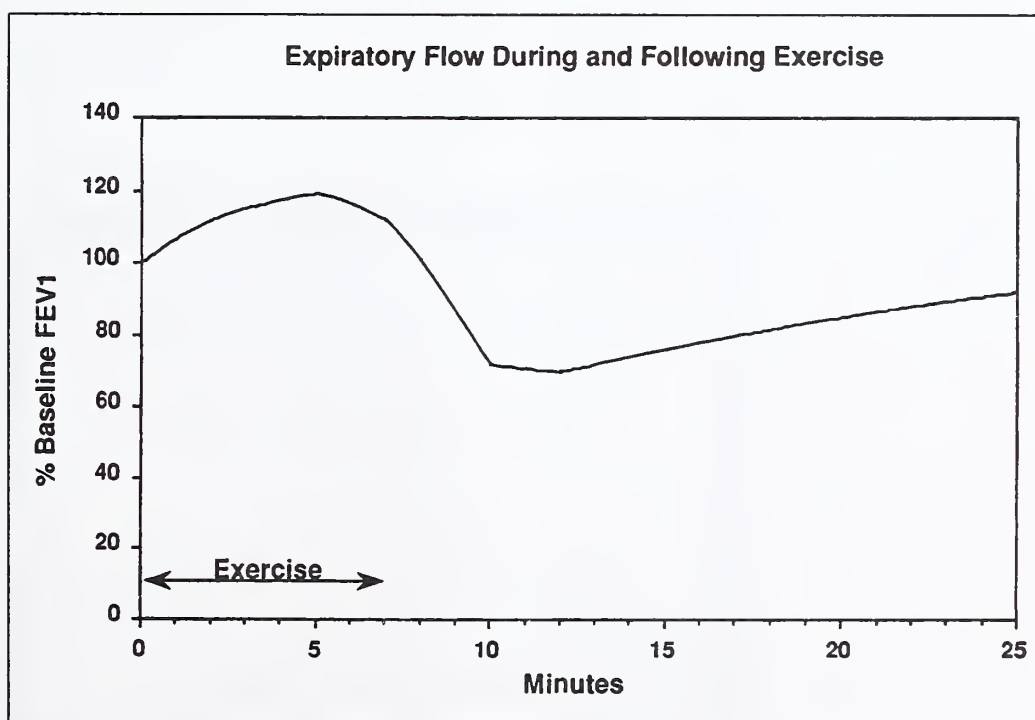
high index of suspicion if someone has no difficulty swimming but has difficulty running, especially in cold weather.

The next step in the diagnostic workup is an assessment of pulmonary function and consideration of bronchial provocation testing. The characteristic pattern of obstructive dysfunction is demonstrated by a low FEV₁, FEV₁/FVC ratio, and reduced specific airways conductance. An increase in the FEV₁ of 15% following inhalation of a beta₂ agonist, confirms reversibility of airways obstruction. However, if expiratory flow rates are within the normal range, bronchoprovocation testing should be considered. Likewise, a reduction in FEV₁ during a bronchoprovocation (methacholine) trial confirms a diagnosis of asthma. Multiple medications, however, can interfere with the methacholine challenge result. H₁ selective antihistamines, calcium channel blockers, long-acting methylxanthines, and alpha and beta₂ agonists and antagonists can all affect provocation testing. Also, other diseases can mimic asthma; therefore, test results must be carefully interpreted.

An alternative approach to diagnosing exercise-induced asthma is to use exercise rather than methacholine as the bronchoprovocative agent. A reduction in FEV₁ or peak expiratory flow rate of 10% or more during exercise is consistent with the diagnosis.^{12,13} The physical activity used to provoke bronchospasm need not be type-specific but should attempt to match the intensity level of the exercise which, by history, had been known to cause the problem. Usually a treadmill is employed for exercise testing but a cycle ergometer can also be used. With a treadmill, the patient exercises for 4-8 minutes at a workload sufficient to increase the heart rate to 80% of predicted maximum or to about 50 to 60% of the subject's predicted maximum oxygen consumption.⁶ Expiratory flow rates, typically the FEV₁, are measured before and 1-2 minutes after exercise is completed and then at 5-minute intervals for at least 15 minutes. Caution may be needed in individuals who have cardiovascular diseases.

TREATMENT

Since exercise is an important part of the psychosocial as well as the physical development in children, it is im-



Typical changes in expiratory flow rates in an individual with exercise-induced asthma

portant to prophylactically treat exercise-induced asthma to allow these individuals an active lifestyle. With individuals in whom exercise is but one of many asthma triggers, daily treatment with an inhaled anti inflammatory medication is beneficial. As the underlying airway inflammation is reduced, the bronchospastic response to exercise diminishes. With individuals in whom the only trigger for asthma is exercise, a number of therapeutic options can control symptoms. Approaches include the use of metered dose inhalers for the acute treatment of symptoms or a prophylactic approach. The latter may be accomplished by pretreatment with medications or with exercise itself. Drugs that have been approved for use by the US Olympic Committee include beta adrenergic agonists, inhaled corticosteroids, oral methyxanthines, and oral antihistamines. The pharmacologic approach is most often used to prevent exercise-induced asthma. The mainstay of this therapy is with inhaled beta₂ agonists. Fast acting beta agonists such as albuterol and bitolterol are especially effective when taken 10-15 minutes before exercise. This approach may prove to be effective in as many of 90% of patients. Typically, 2 puffs of albuterol from a metered dose inhaler will prevent exercise-induced asthma for approximately 2 hours. However, the duration of action of these agents is short-lived, lasting only a few hours. Thus, repeated administrations may be required if the activity is prolonged. Longer acting beta agonists such as salmeterol can be effective for up to 12 hours. This drug should be taken 30-60 minutes before exercise. Patients using this drug every 12 hours should not however take extra doses before exercise.

Cromolyn and nedocromil have been used as alternative therapeutic approaches. They can attenuate the bronchoconstrictor response to exercise with an effective duration of about one to two hours. These drugs are generally not as effective as beta agonists in that they prevent exercise-induced bronchospasm in about 40% of patients.¹⁴ Both cromolyn and nedocromil can be given by metered dose inhaler or nebulizer. If 2 puffs are not sufficient to prevent broncho-

...if someone chooses to be sedentary, they may do so because of the discomfort associated with exercise-induced bronchospasm.



spasm, 4 puffs may be helpful. These agents have essentially no side effects. In addition, they block the late phase reaction to exercise. These drugs are usually not used for rescue once bronchospasm occurs. Combination of a beta₂ agonist and cromolyn may be more helpful than using either one alone. In this instance, the patient should take the cromolyn 5-10 minutes after taking the beta agonist. Ipratropium has also been used to manage exercise-induced bronchospasm. Since bronchodilation with anti-cholinergic agents are of slower onset, they should be taken 60-90 minutes before the onset of exercise. Other agents that are not as commonly used include theophylline and inhaled corticosteroids. When inhaled corticosteroids are used as a sole agent, they may not prevent exercise-induced asthma. They can be used with a beta₂ agonist in more chronic severe asthmatics in decreasing inflammatory response and decreasing vascular permeability. Exercise itself can be used as a prophylactic agent for exercise-induced asthma. Typically, there is a refractory period following exercise in which the airways do not constrict with further exercise. When repetitive episodes of exercise are performed within 40 minutes or less of each other, the degree of bronchial constriction progressively decreases. Exercise is the only trigger for asthma that can induce this phenomena of tachyphylaxis.⁶ This reduction in bronchial reactivity then may be used to the individual's advantage as a prophylactic measure. For example, the simple act of warming up before exercise can help diminish the bronchospastic response and provides a useful strategy in children and adults who participate in organized or scheduled physical exertion (i.e. physical education class,

sports, exercise class, running, jogging) However, a warm up is not possible before unexpected periods of exertion (i.e. running for a train).

Finally, the recent advent of leukotriene synthesis inhibitors and of leukotriene-receptor antagonists provide the clinician a new means of preventing exercise-induced asthma. These drugs may be protective as long as 20 to 24 hours following dosing. Individuals taking these medications may be less likely to require beta agonist rescue therapy during exercise. The exact role of this class of medication in preventing exercise-induced asthma still needs to be clarified.¹⁵

To summarize, exercise-induced asthma is common among children and young adults. Some individuals may not trace their exercise intolerance to exercise-induced bronchospasm. The diagnosis of exercise-induced asthma is suggested by clinical history and a reduction in FEV₁ by at least 15% with methacholine challenge or by 10% with exercise challenge. Prophylactic treatment with inhaled agents 15-30 minutes prior to exercise is usually effective in preventing symptoms. Bronchospasm may also be prevented if individuals warm up before more vigorous exercise. Patients with exercise-induced asthma should be encouraged to engage in physical activities rather than adopt a sedentary lifestyle. Thus, selecting sports such as swimming rather than running or playing ice hockey may be more rational choices for these individuals.

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on her retirement

We thank her for many years of dedicated service
and wish her well in her new literary career

We will continue our tradition of excellence in patient
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MARCH 29 & APRIL 5, 5:00 - 9:00 PM

The Brown University AIDS Program, with the assistance of the New England AIDS Education and Training Center, is sponsoring a two-part program to train primary care providers in issues surrounding AIDS and Human Immunodeficiency Virus (HIV) infection. Our goal is to facilitate comfort in the evaluation and management of individuals with HIV infection, and to increase knowledge of resources available for appropriate triage.

TOPICS TO BE COVERED ON MARCH 29 INCLUDE:

- Recognizing and monitoring HIV infection
- Infection control practices
(One hour bloodborne pathogen CME offered*)
- Strategies for HIV prevention

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HIV, Infectious Diseases, and Competitive Athletics

Alexander A. Feller and Timothy P. Flanigan, MD, MPH

The interplay between infectious diseases and competitive athletics is an emotional one filled with half-truths and myths. Much of the sports-viewing public is acquainted with the HIV disclosures of basketball star Earvin "Magic" Johnson, diver Greg Louganis, and boxer Tommy Morrison. These announcements gave a public face to the reality that there are athletes competing today who are carriers of infectious diseases, including human immunodeficiency virus (HIV), hepatitis B (HBV), herpes, and other infections. Many members of the lay, scientific, and athletic communities do not have a full understanding of the sports medicine implications of infectious diseases. Medical reality and a hard-eyed appraisal of public health risk should govern recommendations to protect the health of infected and non-infected athletes.

INFECTIOUS DISEASE TRANSMISSION IN SPORTS

Much of the concern in the scientific and athletic community has centered on the potential transmission of HIV via athletic contact. No transmission of HIV in the athletic setting has been documented. Physicians in Varese, Italy, reported an HIV seroconversion after a head-to-head collision between a seronegative player and an intravenous drug user during a soccer match.¹ Officials later could not confirm that the individual had not been infected at a drug rehabilitation center at which he worked. Two separate "sport-like" transmissions have been verified by the Centers for Disease Control, both fistfights, with one involving a nasal hemorrhage bleeding into an open cut on the forehead of a previously uninfected man.² Italian researchers have also reported a dual hepatitis B (HBV)-HIV transmission when a dually infected motorist head-butted a previously seronegative man after a car accident.³

The risk of HIV transmission in the sports arena is hence possible but slim. No evidence exists that HIV can be transmitted via sweat or saliva. Current laboratory techniques using polymerase chain reaction for HIV RNA and proviral DNA indicate that HIV is not present in eccrine sweat.⁴ A statistical estimate of the overall transmission risk of HIV in professional football is 1 per 85 million game contacts,⁵ due to very low HIV prevalence and low risk of blood-borne exposure in this contest.

Though the risk of an on-field HIV transmission may be small, physicians treating athletes should be aware that outbreaks of blood-borne diseases can and do occur. HBV is more concentrated and sturdy in the blood and more likely to be transmitted effectively than HIV. In the early 1960s, 600 Swedish rough terrain orienteers were infected with HBV after a competition in which the athletes received frequent skin abrasions and then, post-event, soaked in a common bath of slowly moving water.⁶ In 1980, five of ten members of a high school sumo wrestling club in Japan developed HBV. The source of the outbreak was presumed to be an asymptomatic HBV carrier who transmitted the virus percutaneously via abrasions incurred during wrestling.⁷

Wrestling-induced herpes (herpes gladiatorum) represents a frequent form of infectious disease transmission due to direct contact. There are 12 reports of herpes simplex (HSV) outbreaks among wrestling and rugby teams, often involving more than one strain of HSV.⁸ In one case, 60 (34%) of 175 high school wrestlers practicing at one training facility became infected with HSV-1; 13 (22%) continued to wrestle after developing a vesicular skin rash.⁹

Contagion by bacterial and fun-

Abbreviations Used:

AIDS	acquired immune deficiency syndrome
DNA	deoxyribonucleic acid
HBV	hepatitis B
HIV	human immunodeficiency virus
HSV	herpes simplex virus
MRSA	methicillin-resistant staphylococcus aureus
NK	natural killer
STD	sexually transmitted disease
URI	upper respiratory tract infections

gal infections may occur in athletes and among their community and athletic contacts. Outbreaks of staphylococcal and streptococcal skin infections among basketball, football, rugby, soccer and wrestling teams have also been reported.⁸ In 1994, seven of 32 members of a Vermont high school wrestling team developed methicillin-resistant staphylococcus aureus (MRSA).¹⁰ Three of 16 Vermont teams and 8 of 26 out-of state teams that wrestled against the team reported skin lesions in team members following competition. Eleven non-wrestling members of the community reporting contact with the team also developed MRSA infection.

EXERCISE AND IMMUNE FUNCTION

The effects of exercise on immune function vary based on the intensity of exercise and immune status of the athlete. A J-shaped curve can characterize the rate of upper respiratory tract infections (URIs) in athletes. Those athletes engaging in moderate exercise have the lowest rate of infection with URIs increasing with greater exercise intensity. The association of moderate exercise and an elevated immune response has been demonstrated in both normally functioning and immunocompromised individuals. According to the American College of

Sports Medicine's guidelines, a physician-prescribed 12-week regimen of moderate exercise enhances immune function and improves cardiorespiratory fitness.¹¹ Exercise has also been demonstrated to increase the release of endorphins and enkaphalins and decrease corticosteroid release, factors possibly related to the exercise-induced reductions in psychological stress.

The beneficial effects of moderate exercise extend to immunocompromised individuals as well. Evidence exists that moderate exercise among HIV-positive individuals can be sustained without large changes in CD-4 count or CD-4/CD-8 ratio.¹² Other studies of both non-symptomatic HIV positive individuals and those with advanced HIV infection and symptomatic AIDS found that exercise led to increases in muscular mass, cardiorespiratory fitness, and decreases in psychological stress. The effects on indices of immune function were either negligent or positive.¹³ Resistance training has also been demonstrated to increase muscle strength, bulk, and muscle function and has been proven to be particularly effective in battling the wasting associated with end-stage AIDS. Positively Fit, an exercise program created in Vancouver, British Columbia, and geared toward HIV-positive individuals, has served as a template for effective interaction between the sports community and local AIDS organizations.¹⁴

Intense prolonged exercise results in a suppressed immune response including decreased circulating leukocyte subset numbers, decreased concentration of lymphocytes, lowered levels of natural killer (NK) cell activity and lymphokine-activated cytotoxicity, lowered secretory IgA in mucosa, and decreased neutrophil and macrophage phagocytic activity.¹³ This paradigm has been verified in studies of elite athletes. One study of professional soccer players found that during their competitive season, neutrophil counts increased and CD-4 counts decreased with changes normalizing during periods of less intense training.¹⁵ Another study of elite swimmers found that, during the training season, serum im-

munoglobulin and IgA levels were lower among athletes than in controls and predisposed toward the development of URIs.¹⁶ The psychological stress associated with elite training may also contribute to this immunodepression. Though no studies of elite HIV-positive athletes have been conducted, the current recommendation for the immunocompromised individual is that moderate exercise is advisable while strenuous prolonged exercise probably is not.

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KNOWLEDGE, ATTITUDES, AND BEHAVIOR OF ATHLETES

There are scarce data concerning the knowledge and attitudes of competitive athletes regarding HIV and other infectious diseases and sports, exercise, and immune function. We conducted a study of 529 Rhode Island high school athletes regarding their knowledge and attitudes of issues relating to HIV, infectious diseases and competitive athletes.¹⁷ Our results suggest that high school athletes lack knowledge about AIDS, especially the risks of infection and avenues of contagion. We also found a significant disparity between the responses of public and private school students and, to some extent, between males and females. A considerable number of both public and private school students favored certain sanctions against HIV-positive individuals in the sports arena. Thirty percent of public and 18% of private school students believed that HIV-infected athletes should not be allowed to compete in contact sports

($p < 0.001$). Fifty-eight percent of all students did not oppose banning HIV-positive trainers from treating athletes. Sixty-nine percent of public and 41% of private school students favored mandatory HIV testing of all athletes. Our results suggest that primary care physicians who treat adolescents and young adults must be aware of their limited knowledge of HIV and infectious disease

In terms of knowledge base, our survey indicated considerable gaps in knowledge including modes of transmission and current understanding of infectious disease and athletics. Forty-six percent of students did not know that herpes could be contracted from wrestling with an infected wrestler. Eleven percent of students believed incorrectly that a vaccine exists for the AIDS virus. A majority of public school (52%) and one-third of private school students (34%) agreed with or expressed uncertainty whether mild exercise was unhealthy for the HIV-positive athlete.

The misconceptions regarding HIV among interscholastic athletes are startling given the documented HIV, hepatitis, and sexually transmitted disease (STD) risk of many male athletes. Since Magic Johnson's seropositive disclosure, awareness, if not knowledge, of HIV and AIDS has increased, particularly among males and blacks. (In one survey, 40% of students reported changing their perception of their own HIV risk.)¹⁸ Nevertheless, HIV risk-taking among athletes is not abating. Intercollegiate athletes consume more alcohol, use condoms less consistently, have more sexual partners, and have more reported sexually transmitted diseases than non-athletes.¹⁹

Intramuscular injection of steroid use represents another risk factor for the development of HIV and other infectious diseases. Between 4% and 12% of high school seniors, many of them wrestlers, football players and strength-sport participants, report using steroids. Another survey of 1,010 intercollegiate athletes calculated that between 2% and 20% of athletes used steroids²⁰ - disturbing numbers given the considerable needle sharing among

users of injectable steroid packages.

These behaviors place athletes at far greater infectious disease risk than does any on-field event. Athletes should be counseled about their sexual risk, warned about the risks of steroid use and needle sharing, and, if insistent about steroid use, advised about needle exchange opportunities.

RECOMMENDATIONS

The National Collegiate Athletic Association, the American Academy of Pediatrics Committee on Sports Medicine, and the World Health Organization have released similar statements on the management of blood-borne infection in competition. Any open wound must be dressed immediately before an athlete can practice or compete. Skin lesions should be examined by appropriate medical personnel to evaluate the possibility of blood-borne transmission. Bloody uniforms are to be treated as a health hazard, necessitating a change in uniform before returning to competition. Finally, "universal precautions" including cleaning wounds with antiseptic, using sterile gloves, decontaminating bloodied training tables and floors, and laundering bloodied or soiled uniforms are now standard in interscholastic, intercollegiate, and professional athletics.²¹ Any decision not to compete should be made after consultation with the athlete's private physician and team physician.

Given the minuscule risk of HIV transmission in competition, neither HIV testing of all athletes nor limiting the participation of the HIV-positive athlete, nor breaching the confidentiality of the infected athlete are warranted as public health measures. The National Basketball Association, National Hockey League, Major League Baseball, and the International Olympic Committee have echoed this opinion. Professional boxing remains the only major exception to the basic rule of respect for the confidentiality and right to compete of the HIV-positive athlete. In 1988, in a decision followed by boxing commissions in many states, the Nevada Athletic Commission mandated HIV testing for boxers, with a

positive test resulting in an automatic disqualification from boxing. The policy is still in effect though clouded by contentious legal parrying involving right-to-privacy issues and calls for boxing to become safer from both an infectious disease and a broader medical standpoint. Amateur fights, for instance, are halted to dress bleeding wounds. Olympic boxers also wear larger gloves, fight shorter bouts, and wear shirts and protective headgear, measures that decrease infectious disease risk and the possibility of more serious injury including brain damage, brain hemorrhage, and internal trauma.

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consume more alcohol,
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Hepatitis B testing is neither widespread nor recommended of all athletes due to the similarly slim, albeit elevated, risk of infection in comparison to HIV. Hepatitis B vaccination is recommended for all athletes and all trainers who have exposure to blood. One of the documented outbreaks of Hepatitis B in the athletic setting occurred among Japanese sumo wrestlers, grappling with much of the skin on their body exposed, who were apparently infected by a fellow wrestler with open wounds, scars, and bleeding. Adhering to universal precautions minimizes the risk of a similar event occurring in a sanctioned athletic setting.

With regard to the viral, fungal, and bacterial skin infections that have led to most of the infectious outbreaks in wrestling, a more stringent policy is necessary. Ten percent of practice and competition time missed by wrestlers is due to skin infections.²¹ Any open

wound and infectious skin condition that cannot be bandaged or otherwise shielded from contact should disqualify an athlete from competition. In addition, the current recommendation is that medical personnel examine the skin over the entire body of all wrestlers before clearing them for participation.²¹

The more rigorous policing of skin infections necessary in sports such as wrestling highlights the fact that distinct diseases require different medical and public safety measures. A blood-borne transmission of HIV or HBV is far more likely to be the result of risky off-field sexual or drug use behavior than to occur in a bloody on-field collision. Strict adherence to universal precautions diminishes the risk of blood-borne exposure even in close contact sports to close to zero.

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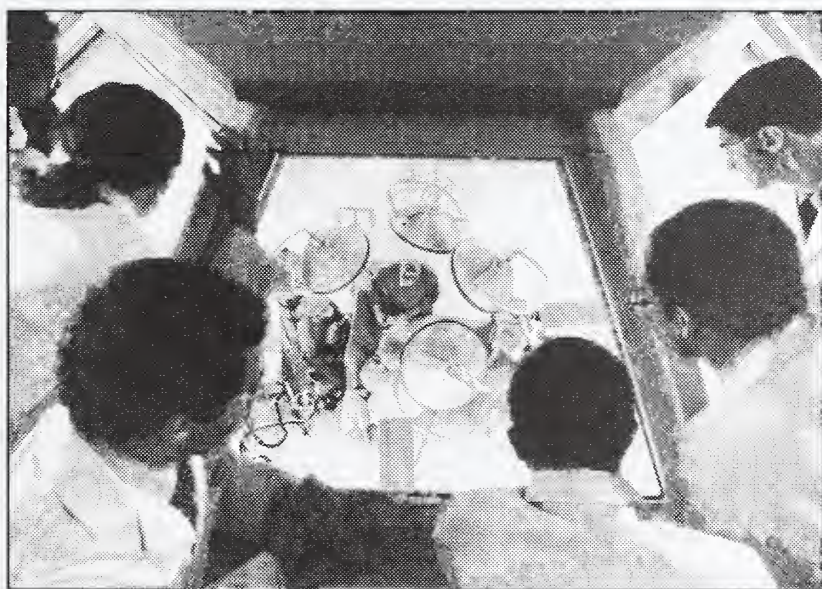
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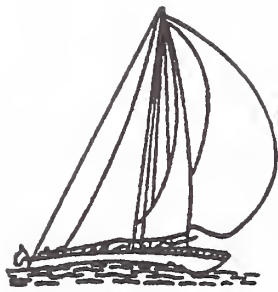
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Get With the Guidelines

Kenneth LaBresh, MD

In 1995 the American Heart Association and the American College of Cardiology published *Comprehensive Risk Reduction for Patients with Coronary and Other Vascular Disease, the Secondary Prevention Guidelines*. The data show that 94% of post-acute myocardial infarction (AMI) patients have LDL exceeding the goal of less than 100. As a matter of practicality they virtually all need treatment and less than 25% are on drug therapy and 11% are at goal.¹ Despite widespread dissemination of the guidelines and the underlying evidence base for reduction of mortality and morbidity, several publications have identified poor adherence to the guidelines in hospitals and outpatient practices.²⁻⁴ Recognizing this gap between what we know and what we do, in 1998 the American Heart Association set the ambitious goal to reduce morbidity, mortality and risk for cardiovascular disease and stroke by 25%. This will be accomplished by striving to improve access to emergency cardiac and acute care treatment, by enhancing disease prevention and management, and by providing the necessary resources to sufficiently achieve these health-related goals. Our prevention and treatment programs will focus much of our attention on implementation of the guidelines, seeking to put into practice what we already know.

Medical systems throughout the United States are under increased pressure to adapt to rapidly changing protocols and regulations. In Rhode Island our acute care hospitals, working with Rhode Island Quality Partners (RIQP) in their 5th Scope of Work project, demonstrated significant improvement in the treatment of AMI for the use of aspirin, B-blockers, and Angiotensin Converting Enzyme Inhibitors (ACEI). The program, however, highlighted the need for additional improvement in B-blocker use and counseling for smoking cessation, and did not address the use of lipid lowering agents which are currently used in less than 25% of this patient population.

"Get With The Guidelines" is a program developed by the New England Affiliate of the American Heart Association (AHA) aimed at assisting health care professionals to implement the comprehensive cardiac risk factor prevention guidelines established by the American Heart Association and the American College of Cardiology in institutions. This program will target patients discharged with

Abbreviations Used:

ACEI	angiotensin converting enzyme inhibitors
AHA	American Heart Association
AMI	acute myocardial infarction
HCFA	Health Care Financing Administration
HEDIS	Health Employers Data and Information Set
JCAHO	the Joint Commission on the Accreditation of Healthcare Organizations
RIQP	Rhode Island Quality Partners

coronary artery disease. The primary focus of this program is to assist hospital teams in developing and implementing protocols designed to meet the need to satisfy the Health Care Finance Administration (HCFA), the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), and the Health Employers Data and Information Set (HEDIS) performance indicators, and more importantly adding to the quality and quantity of life of our many Rhode Islanders with vascular disease. The American Heart Association New England Affiliate will provide hospitals with the educational tools and resources necessary to make this program a success. The guidelines can be obtained from the AHA office in Providence or at the Americanheart.org web site. Furthermore, the 10 acute care hospitals are developing care maps and standing orders to implement these guidelines.

We recognize that there are other initiatives underway to improve cardiovascular care. By partnering with other successful programs such as HCFA's 6th Scope of Work currently being implemented by RIQP, the American Heart Association seeks to enhance and expand these efforts.

"Get With The Guidelines" is designed to:

- assist with building consensus throughout hospitals
- develop flexible care maps
- utilize data collection resources to avoid duplication

This is very much a TEAM project. Possible members of a hospital-wide team include: Medical Director/Associate, Cardiologists, Case Managers, Quality Assurance Di-

rector/Managers, Pharmacy Directors, Cardiac Rehabilitation Nurse, Patient Education Director, Data Information Manager/Analyst and Wellness Coordinator.

As medical practitioners, we and our patients are the ultimate team that will determine the success of this initiative. After helping to create a successful system for the initiation of treatment, we need to insure its use and help our patients to adhere over the long term. Remember that these proven interventions: aspirin use, B-blockers, ACE inhibitors, lipid lowering, blood pressure control, exercise and smoking cessation are life saving treatments which can stem the epidemic which now kills two thousand of our family members, friends and neighbors in Rhode Island every year.

Kenneth LaBresh, MD, is President, American Heart Association, New England Affiliate; Blackstone Cardiology Associates, Pawtucket, Rhode Island.

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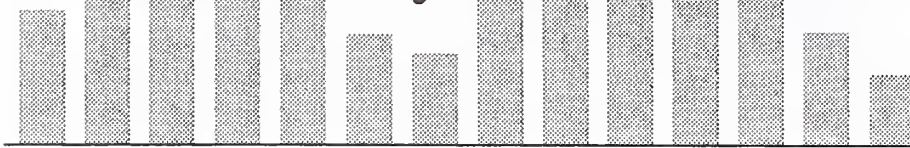


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Head Injuries Sustained During Sports and Recreation

Jay S. Buechner, PhD, Mary C. Speare, MA, David Hamel, MPA, Janice Fontes, MA

During the past two decades, the acute medical treatment for traumatic brain injuries has improved considerably. Now, many patients survive after experiencing severe head injuries that would have proven fatal earlier. These persons require rehabilitative services that are different in kind and duration from those needed by most other injury victims. Recognizing the need to plan for, provide, and evaluate injury prevention activities and the services needed by head injury survivors, the Rhode Island General Assembly established a statewide Traumatic Brain Injury (TBI) Registry in 1986. This report presents statistics from the registry on serious head injuries among Rhode Island residents during 1996 and 1997 that were sustained during participation in sports or recreational activities.

Methods

The TBI Registry identifies cases of head injury that result in death or admission as a hospital inpatient through examination of (1) death certificate data, (2) hospital discharge data, (3) direct data submissions from hospitals to the registry, and (4) hospital trauma registry data. For 1996 and subsequent years, registry staff have abstracted data from hospital medical records and State Medical Examiner records for cases meeting the case definition established by the Cen-

ters for Disease Control and Prevention (CDC).¹ Where relevant data sources are available, Rhode Island residents sustaining head injuries out of state have been included in the registry.

Head injuries sustained during sports or recreation were identified from information on the etiology and external cause of injury. Any case with an etiology code for a specific sport or with an external cause of either a fall during sports or collision during sports was defined as sports-related. Any case with an external cause related to bicycles, swimming, recreational boating, snowmobiles, off-road motor vehicles, horseback riding, or other recreational activity or identified as occurring at a place of recreation was defined as recreation-related. United States Bureau of the Census estimates were used as population denominators for rates.²

Severity of injury was determined based on information concerning (1) death at the injury scene or prior to hospital admission, (2) the patient's Glasgow Coma Score at admission, and (3) the patient's level of consciousness at admission. Based on these items, injury severity was ranked as follows: death, coma, moderate impairment of consciousness, and minimal or no impairment of consciousness.

Results

Rhode Island residents sustained a total of 1,378 head injuries during 1996 and 1997 that met the CDC case definition. Of these, 43 (3.1%) were sports-related and 108 (7.8%) were recreation-related. (Figure 1) [Included in the "All Other" category were falls, vehicle accidents, and physical assault.]

Younger persons and males were at elevated risk for head injuries related to sports and recreation. (Figure 2) Incidence rates were greatest among those ages 14 and younger; at higher ages, the incidence rate decreased with age until the age group 44 years and older, where it was less than one-tenth the rate among children and young adolescents. For other head injuries, the age pattern reflected the frequency of falls among the very young and the elderly and the frequency of motor vehicle crashes among adolescents and adults. By gender, males of all ages were three times as likely as females to sustain head

Abbreviations Used:

CDC	Centers for Disease Control and Prevention
TBI	traumatic brain injury

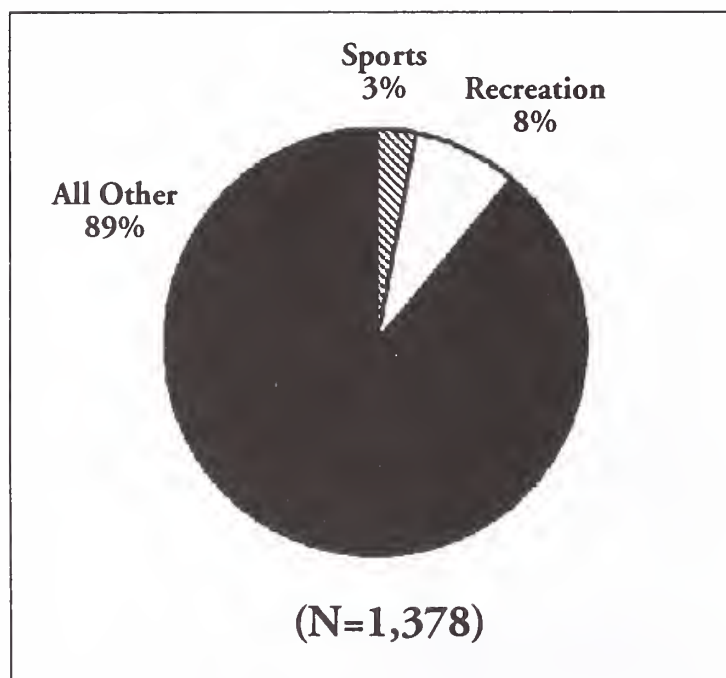


Figure 1. Traumatic Brain Injuries by Cause of Injury, Rhode Island, 1996-1997.

Table 1. Distribution of Severity* of Traumatic Brain Injury by Cause of Injury, Rhode Island, 1996-1997.

Severity*	Cause of Injury		
	Sports (N=43)	Recreation (N=108)	Other (N=1,227)
Death	0%	6%	2%
Coma	2%	7%	15%
Moderate impairment	9%	13%	13%
Minimal or no impairment	88%	75%	70%

*Based on death or impairment of consciousness

Note: Percentages may not total 100 due to rounding.

injuries during sports and recreation.

Overall, head injuries due to sports and recreation were slightly less severe than head injuries sustained from other causes. (Table 1) Three-quarters or more of them resulted in minimal or no impairment of consciousness, compared to 70% of other head injuries. One exception to this general finding is that a relatively high, but not statistically significant, proportion (6%) of head injuries related to recreation resulted in death.

Discussion

One in nine serious head injuries in Rhode Island results from participation in sports or recreational activity. These injuries occur disproportionately among the very young and therefore have greater long-term impact on the individual, his or her family, and the state's rehabilitation and education systems.

Because of their numbers and the resources needed to treat them, head injuries have received increasing attention

sustained and expanded primary prevention efforts targeted at TBI and by the development and implementation of a comprehensive statewide program to meet the documented needs of persons with traumatic brain injuries.

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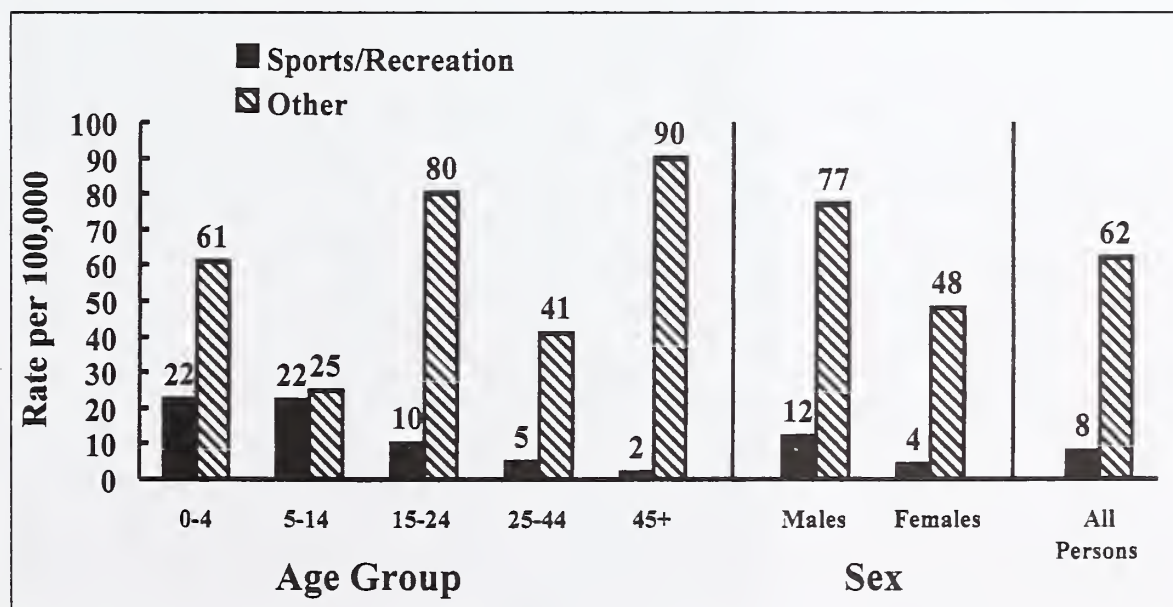


Figure 2. Traumatic Brain Injuries per 100,000 Population, by Age Group, Sex, and Cause of Injury, Rhode Island, 1996-1997 (Annual Average Rate)





Bone Mineral Density Assessment

Jonathan P. Vaccaro, MD, and Susan G. Leffler, MD

[PART ONE OF A TWO-PART SERIES]

Despite increasing professional and public awareness of osteoporosis, the management of this disease has been confined mainly to specialists. Yet given the ubiquitous nature of the disease and recent improvements in diagnostic testing and safer treatment options, the primary care physician needs to be cognizant of the methods to diagnose, monitor, and treat osteoporosis.

This two-part review is intended to provide an introduction to bone mineral density assessment (BMD). Part one will provide a brief review of the definition and epidemiology of osteoporosis, then describe methods for measuring bone mineral density, and when to use them. Part two will review the interpretation of test results, continued monitoring of bone mineral density, and other management issues.

A SILENT KILLER

Osteoporosis is characterized by low bone mass and micro-architectural deterioration which leads to bone fragility and to an increased risk of fracture.^{1,2} In 1994 the World Health Organization (WHO) defined osteopenia, osteoporosis, and severe osteoporosis in terms of BMD, using standard deviations below the young adult mean as the unit of measurement. (Table 1) The National Osteoporosis Foundation (NOF) used a similar approach to define cutoff points for pharmacologic intervention: BMD T-scores less than -2.0 standard deviations in women with no known risk factors for osteoporosis, and BMD T-scores less than -1.5 standard deviations with known risk factors.

As one of the most prevalent conditions associated with aging, osteoporosis is a major health problem. The lifetime risk of osteoporosis is greater than a woman's combined lifetime risk of ovarian, breast, and endometrial cancer, and a man's lifetime risk of prostate cancer. The most common clinical manifestations of osteoporosis are fractures and their complications. Fractures generally occur about the hip, spine, wrist, and proximal humerus. About 500,000 spine fractures, 250,000 hip fractures, and 240,000 wrist fractures occurring in the United States each year are believed to be caused by osteoporosis.²⁻⁴ Hip fractures are especially disastrous, because up to 20% result in death, and another 50% result in significant disability at one year post injury. Osteoporosis is considered a "silent killer," because clinical

Abbreviations Used:

BMD	bone mineral density
DEXA	dual energy x-ray absorptiometry
NOF	National Osteoporosis Foundation
QCT	quantitative computed tomography
WHO	World Health Organization



Figure 1. Incidental findings of thoracic kyphosis and wedge compression deformity.

Table 1. World Health Organization bone mineral density criteria for osteoporosis		Table 2. National Osteoporosis Foundation criteria for performing bone mineral density testing
Classification	T-Score	<div>1. All postmenopausal women less than age 65 who have one or more additional risk factors for osteoporosis (besides menopause).</div> <div>2. All women age 65 and older, regardless of additional risk factors.</div> <div>3. Post-menopausal women who present with fractures.</div> <div>4. Women who are considering therapy for osteoporosis if BMD testing will facilitate the decision.</div> <div>5. Women who have been on hormonal replacement therapy for prolonged periods.</div>
Normal	> -1.0 SD	
Osteopenia	< -1.0 SD, ≥ -2.5 SD	
Osteoporosis	< -2.5 SD	
Severe Osteoporosis	< -2.5 SD with fragility fractures	

Table 3. QCT versus DEXA	
Preferred Modality	
QCT	DEXA
<div>Prior QCT</div> <div>Patient weight <105 pounds</div> <div>Patient weight 200-400 pounds</div> <div>Children</div> <div>Severe scoliosis</div> <div>Severe DJD of spine</div> <div>Prior lumbar spine surgery (e.g., laminectomies, Harrington rods, and pedicle screws)</div> <div>Severe aortic calcification</div>	<div>Prior DEXA</div> <div>Patient weight >300 pounds</div> <div>“Average” patient without prior back surgery, scoliosis, or DJD, since 2 sites are measured.</div>
Cannot Perform	
QCT	DEXA
<div>Pregnancy</div> <div>Weight >400 pounds</div>	<div>Pregnancy</div> <div>BE within one week</div> <div>Nuclear med scan within one week</div> <div>Same day IV contrast</div>
Major Differences	
<div>1. QCT is more sensitive for following pharmacologic intervention if patient has scoliosis, osteoarthritis, or prior surgery of lumbar spine.</div> <div>2. With serial measurements, the spine will be far more sensitive to detecting changes in bone mass than the hip.</div> <div>3. DEXA has the advantage of screening more than one site.</div> <div>4. DEXA can perform forearm analysis. This is particularly relevant for evaluating cortical bone loss seen in hyperparathyroidism and hyperthyroidism.</div> <div>5. Some DEXA units (e.g. Lunar) can obtain a whole body analysis of total BMD as well as whole body fat composition.</div>	

manifestations do not present until an advanced disease state. Indeed, the pain comes from the fractures, not from the osteoporosis.

WHO IS AT RISK?

Numerous risk factors have been reported which may help predict patients with low bone mass or with increased fracture risk.^{1,2,5} Some of the common risk factors, such as

age, sex, race, and family history, cannot be modified. Others, such as smoking, alcoholism, low body weight, estrogen deficiency, poor calcium intake, vitamin D deficiency, lack of exercise, and frequent falls are potentially modifiable.

In assessing risk, it is important to consider contributing factors such as known or unknown medical disease and drug therapy. The most common silent or unsuspected causes of secondary bone loss in elderly women are hyperparathyroidism, hyperthyroidism, vitamin D deficiency and multiple myeloma. Common prescription medications associated with bone loss include anticonvulsants, glucocorticoids, heparin, and excessive thyroid hormone used for suppressive treatment.

Anyone with a prior fracture at any site is at increased risk of subsequent fracture at any site.^{4,6} A prior atraumatic fracture indicates a reduction in total bone mass of at least 30%. The earlier the age of fracture, and the greater the number of fractures, the greater the subsequent risk. A previous vertebral fracture increases the risk of additional vertebral fracture by at least two-fold. A wrist fracture doubles the risk of hip fracture and triples the risk of vertebral fracture. Thus, documentation of a prior atraumatic fracture at any site is important. Likewise, further evaluation of any unsuspected vertebral fractures demonstrated on a lateral radiograph of the thoracolumbar spine is imperative. (Figure 1)

WHO SHOULD BE TESTED?

Patients who will most benefit from BMD assessment are determined by the individual's risk profile. At the same time, the assessment of bone mass is justified only in those cases in which the result obtained will influence decisions about treatment, regardless of known risk factors.

In 1998, the NOF published specific criteria for performing BMD testing, based on clinical parameters and risk factors. (Table 2) The NOF asserts that having two or more risk factors places a patient at a greater than 30% increase in fracture risk at any age.¹

The significance of osteoporosis in men should not be overlooked.⁷ Assessing clinical risk factors for osteoporosis in men is comparable to assessing clinical risk factors for osteoporosis in women. Age greater than 65, smoking, and regular alcohol use may contribute significantly to osteoporosis risk.

WHICH ANATOMIC SITE SHOULD BE ASSESSED?

Since osteoporosis is a systemic disease, and bone loss occurs at all sites, measuring BMD at any skeletal site has value in predicting fracture risk.^{2,4,6} Thus a single measurement obtained in the hip, spine, or wrist may be appropriate in younger people with no known risk factors. Measurement at multiple sites has certain advantages, however, especially in the elderly where the distribution of osteoporosis may be heterogeneous. Further, measuring BMD at the site of biological relevance predicts fracture at that site most accurately.⁶ Consider three examples:

1. Since hip fractures in the elderly have the highest morbidity and mortality, evaluating that site has the greatest clinical relevancy.

2. The subtle changes in trabecular BMD that occur in the immediate post-menopausal period or that occur as a result of therapy are often more marked in the spine and can be detected earlier at that site than in the hip or wrist.
3. Cortical bone resorption may be more pronounced in certain diseases such as hyperthyroidism or hyperparathyroidism. Forearm measurements are considered better indicators of cortical bone loss than measurements at other sites.

WHICH EXAM IS BEST TO ORDER?

A number of densitometers provide reliable assessment of bone mass. These evaluate BMD either centrally in the axial skeleton (e.g., vertebral body) or peripherally in the extremities (e.g., forearm, finger, heel). Densitometry measurements of the axial skeleton are considered the most sensitive as this evaluates highly metabolically active trabecular bone. At the same time, hip BMD is the best predictor of hip fracture and predicts fracture at remote sites as well.^{2,4}

Peripheral bone mass measurements in the appendicular skeleton may be performed by radiographic densitometry, dual energy x-ray absorptiometry (DEXA), quantitative computed tomography (QCT), or sonography. Depending on the machine, these techniques measure bone density in the finger, hand, forearm, or heel. Since early bone loss in osteoporosis occurs axially, techniques measuring the appendicular skeleton are less preferred. Approximately 10% of those patients with normal peripheral BMD will have central osteopenia or osteoporosis. However, low cost and portability contribute to its popular use as a "screening" exam. While peripheral BMD measurements are useful for screening, central BMD measurements are necessary for monitoring response to therapy.

DEXA is the most widely available method for diagnosing osteoporosis. A typical DEXA examination consists of two-site BMD measurements: the proximal femur and anteroposterior lumbar spine. Lateral lumbar spine, distal radius, and total body BMD can also be determined by this method. DEXA scanners can also determine body composition by measuring the amount of regional and total lean and fat tissue. Advantages of DEXA include a low x-ray dose (equivalent to one-tenth of a chest radiograph), ease of use, and rapid scan time.

QCT also evaluates BMD of the spine and can be used to assess peripheral forearm measurements. QCT is unique in that it can selectively measure trabecular bone and provide a volumetric density in grams per cubic centimeter (versus DEXA, which measures gm/cm²). Since trabecular bone is more metabolically active than cortical bone, QCT is a more sensitive method for detecting serial changes in BMD. Additional advantages of QCT over DEXA include measurements that are not affected by degenerative disease, scoliosis, or atherosclerotic disease. (Table 3)

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Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report

Provisional Occurrence Data
from the
Division of Vital Records

Underlying Cause of Death	Reporting Period			
	Feb. 1999	12 Months Ending with Feb. 1999		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	279	3,031	306.1	3,760.5
Malignant Neoplasms	180	2,504	252.9	6,823.0**
Cerebrovascular Diseases	40	569	57.5	808.5
Injuries (Accident/Suicide/Homicide)	25	361	36.5	7,162.5
COPD	67	445	44.9	352.5

Vital Events	Reporting Period		
	August 1999	12 Months Ending with August 1999	
	Number	Number	Rates
Live Births	1,135	13,296	13.4*
Deaths	798	9,843	9.9*
Infant Deaths	(14)	(92)	6.9#
Neonatal deaths	(10)	(69)	5.2#
Marriages	926	7,684	7.8*
Divorces	159	2,972	3.0*
Induced Terminations	413	4,857	365.3#
Spontaneous Fetal Deaths	47	1,021	76.8#
Under 20 weeks gestation	(45)	(953)	71.7#
20+ weeks gestation	(2)	(68)	5.1#

**Excludes one death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population

Rates per 1,000 live births

THE RHODE ISLAND MEDICAL JOURNAL

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NINETY YEARS AGO

[FEBRUARY, 1910]

Arthur H. Harrington, MD, Superintendent of the State Hospital for the Insane, in Howard, RI, discussed the challenge of the growing Hospital census. Between 1890 and 1908 the average daily number of patients had risen 101%. (In 1890 the annual average daily count was 507; by 1908 it had risen to 1204). He warned that "overcrowding of wards ... undoubtedly retards, if it does not actually prevent, recovery in some cases." In the debate over hospital care versus custodial care, he came down on the side of the former, citing Pinel's discharge of 50 insane persons from chains (the patients did not deteriorate further) and the work of Dr. Charles Bancroft from the New Hampshire State Hospital (an "alienist of national repute"), who demonstrated that patients with proper care might get better. Accordingly, Dr. Harrington called upon the state to build a "suitable physical plant" for the care of the mentally ill.

In "State Commitment of the Insane in Rhode Island: A Barbaric Scandal," Dr. John E. Donley contrasted the plight of the insane man of means against his impoverished counterpart: "If he or his relatives possess four dollars per week wherewith to defray the expenses of care and treatment, he may be committed privately, and hence without notoriety or publicity, to the State Hospital for the Insane at Howard. This is proper and eminently as it should be....But ...if this patient is poor, if to his insanity he adds the poverty which may have produced it...Not then may he hope to be treated humanely as a man sick in mind....Before he may be sent to the Hospital for the Insane he must be brought into court and subjected to the insult of a quasi-criminal trial."

FIFTY YEARS AGO

[FEBRUARY, 1950]

George Waterman, MD, in the Providence Medical Association annual address, cited the open meeting to discuss the controversy between the Hospital Service Corporation (Blue Cross) and the Medical Society's Physicians Service Committee as a key event of the past year. He also reported on Society committees (Air Pollution, Food Handlers, Medical Milk Commission, Diabetic Detection).

Arthur Kern, MD, described a case of "Linear Psoriasis," an extremely rare occurrence in a four-year-old girl,

who first showed symptoms at age 6 months. Treatment consisted of roentgen-ray therapy.

TWENTY FIVE YEARS AGO

[FEBRUARY, 1975]

In Message from the Dean, Pierre M. Galletti, Vice President, Biology and Medicine, at Brown, discussed "Medical Ethics: How Much Can Be Taught?" In response to "a growing... recognition that the human dimension may be lost, rather than gained, in the process of medical education," Brown had recruited from the Departments of Philosophy, Religious Studies, Biology and Medicine faculty pairs (non-medical and medical) to lead germane University courses (e.g., Ethical Problems in the Field of Mental Health).

RI Tel-Med Program was explained. Patterned after a program developed by the San Bernardino (CA) County Medical Society, RI Tel-Med (spearheaded by the RI Medical Society, with the Department of Health, Blue Shield, and the Council for Community Services) provided free recorded messages on health topics to callers.

Frank W. Sullivan, MD, asked, "Senator Bennett: Where Are You?" Dr. Sullivan was skeptical of the P.S.R.O., included in the Social Security Amendment of 1972 (and credited to Senator Bennett). "Regardless of what the good Senator believed or wanted us to believe about this 'exciting' piece of legislation, it has begun to dull... While Wallace Bennett settles into retirement in his native Utah, medicine is left with the implementation of his cumbersome 'brain-child.'"

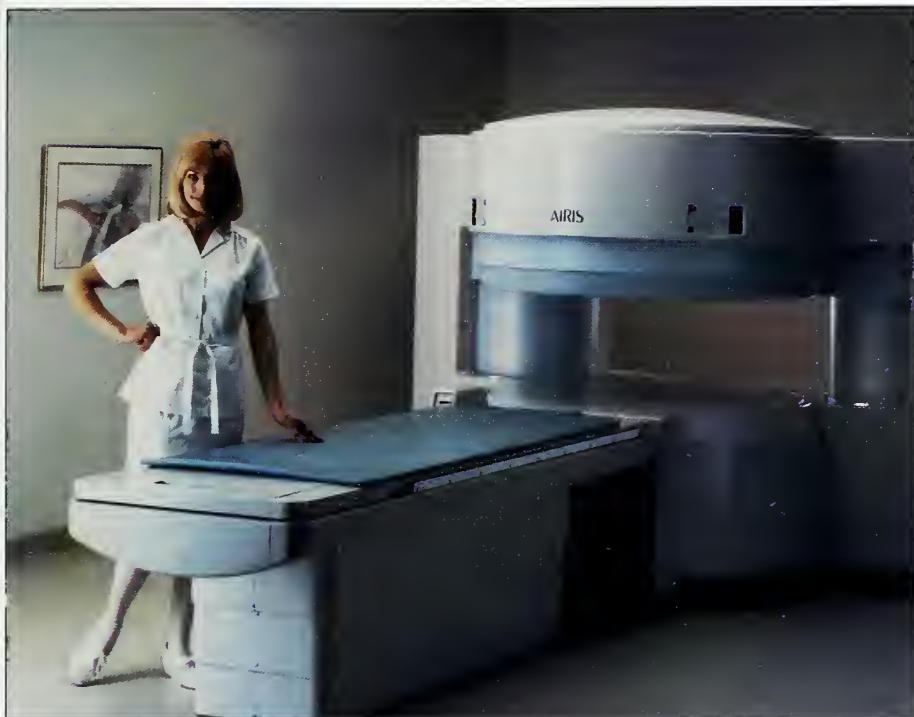
Thomas F. Kelleher, Associate Justice, Supreme Court of Rhode Island, reviewed the structure of the courts, focusing on two major malpractice cases. He reassured readers: "the quintet that occupies the 7th floor is not some radical anti-medical cabal that is out to do you and your profession in..."

Philip J. Rubin, MD, and Stephen H. Zinner, MD, in "An Antibiotic Update: New Penicillins and Cephalosporin,"

cautioned, "...the decision to use a new medication should be based on specific individual clinical situations."



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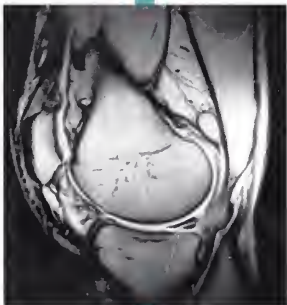
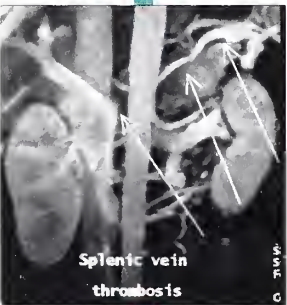
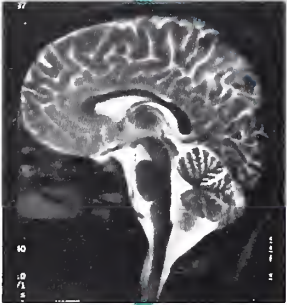
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Cover: “Contemplation,” watercolor and ink, by Zane C. Sherman, Jr., A Providence artist, Zane Sherman Jr. learned to paint with his left hand after a stroke twenty years ago. He has exhibited at Very Special Arts Rhode Island and the Rhode Island Watercolor Society.

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COMMENTARIES

Second Opinions



A relative moved to New York carrying the diagnosis of ulcerative colitis. “I doubt it,” said the new gastroenterologist. “Well I had bloody diarrhea, a barium enema and a colonoscopic evaluation and the gastroenterologist thought it was U.C.” “Well, I’m not so sure.” I think we can cut back on some of these medications. A few weeks later, following a bout of bloody diarrhea and colonoscopy, a diagnosis was rendered. “It looks like you have ulcerative colitis and really do need those medications.” When the New York gastroenterologist moved to New Jersey, the patient found a new specialist, who again doubted the diagnosis and repeated all tests.

What interested me in this were the similarities to my own experiences, less so in recent years, with access to diagnostic tests more limited. It used to be a knee jerk reaction in certain

referral centers to a) immediately assume the local expert was probably wrong, especially if the history was in any way atypical, and b) repeat all tests at the local center without reviewing the old studies. Often new and unnecessary tests were added to the mix, “just to be sure.” Some patients like this reassurance, that two specialists arrive at the same conclusion, virtually independently, the second opinion not really taking the first into account. Some, like my relative, simply wonder why a diagnosis can’t be made and passed on from one doctor to another, not endlessly rediscovered. I must say that this has been one of the few positive outcomes of managed care.

My own discipline, neurology, is less procedure-driven than many others and the imaging studies are often as good at the local level as they are at the tertiary center. The interpretations, of course, vary in quality so one merely

has to request a scan to review rather than repeating it.

Consultants see patients referred by PCPs, patients who are self-referred seeking a second opinion (usually hoping it will be different than the first) and patients referred by other specialists in the field. Generally I’ve found that the more one knows about one area the less reliant one needs to be on tests. When my patients go for their third and fourth opinions I am often struck by how often repeat testing is used more as a crutch for the doctor than a tool. “Well, I tested you every which way” and although none of the tests were very relevant, “it looks like you really do have that disorder.”

We consultants must do a better job of treating our colleague specialists with greater respect. They may know more than we do.

— Joseph H. Friedman, MD

He That Hath Clean Hands

Upon completion of his second expedition to the New World, Columbus returned to Spain with a cargo of precious metals, artifacts and botanical curiosities. One of the exotic objects brought back was a heavy black ball of dried tree sap, called *caoutchouc* and said to have been employed by natives for recreational purposes. The archivists who documented the Columbian treasures noted that when the ball was dropped it rebounded as though it were alive. For three centuries the gummy product remained unexploited until the English chemist, Joseph Priestley, noted that when it was rubbed against paper surfaces it erased pencil marks, hence its newer name, India-rubber.

The wider use of rubber beyond idle amusement or erasure awaited the discovery by Charles Goodyear, in 1839, that when crude rubber was heated to 120 degrees Centi-

grade in the presence of sulphur compounds [a process he called vulcanization] it formed a thermostable, durable and elastic product suitable for membranes and other products requiring both impermeability and pliability. Another fifty years passed before someone suggested that it be used to manufacture gloves for physicians.

Historically, few surgeons tolerated gloves; but in 1758, a German obstetrician, J. Walbaum, devised a hand-covering made of the intestinal wall of sheep. His glove covered three fingers and the back of his hand; and it was layered with grease to facilitate the manual extraction of the newborn baby. [Midwives had commonly applied lubricating substances such as lard or olive oil on their hands when delivering babies.] Walbaum’s contrivance was conceived solely to ease the movements of his hands.

Syphilis, by the 19th Century, was accepted as a contagious disorder. Midwives and physicians learned this harsh reality personally when they often developed syphilis of their hands following internal examination of women with the disease. In 1808 the Viennese dermatologist Josef Plenck advocated that a thin barrier be placed between the examining hand and the patient's body as a means of lessening what had become an occupational hazard; he suggested that the hand be enveloped in a globular sheath using the bladder of a horse.

During the next few decades a number of glove-like devices were contrived, some of leather, some of silk. Their stated purpose was either as a lubricant carrier or as a protection for the physician or midwife against infectious disease. Bulky leather gloves, however, made palpation and suturing more difficult and were universally rejected. In 1842, Sir Thomas Watson, one of England's leading physicians, wrote: "In these days of ready invention, a glove, I think, might be devised which should be impervious to fluids and yet so thin and pliant as not to interfere materially with the delicate sense of touch required in these manipulations." Watson's article was the first to recognize that infection may also pass from the contaminated hands of the physician to the examined patient. Watson, whose wife had recently died of childbed fever, henceforth became a fervent advocate of clinical antisepsis.

An article in an 1847 issue of *Lancet*, the British medical journal, took note of the fact that the examining hands of physicians were regularly infected particularly at sites of prior scratches or sores. The author recommended the use of astringent agents such as silver nitrate applied to the hand before undertaking examinations and, as an afterthought, the possibility of enclosing the examining hand in a protective glove. In the following year *Lancet* contained an article suggesting that thin membranes made from *caoutouc* [derived from the Brazilian Hevea tree] or *gutta percha* [from the Malaysian Palaquium tree] might be suitable for glove manufacture.

In a curious way, Lister's immense contributions to antiseptic surgery served to suppress further development of rubber gloves. Lister contended that his meticulous antiseptic procedures within the operating room precluded the need for gloves, masks or sterile gowns. Surgeons reconsidered the merit of rubber gloves, however, when experiments demonstrated that viable bacteria remained on their hands despite vigorous scrubbing and immersion in antiseptic solutions.

In 1889 William Stewart Halsted, a prominent American surgeon, noticed that his operating nurse had developed a severe skin rash caused by the harsh antiseptics she used in repetitive hand-washing. In his diary he wrote: "As she was an unusually efficient woman, I gave the matter my consideration and one day in New York requested the Goodyear Rubber Co. to make two pairs of rubber gloves with gauntlets." The gloves proved to be eminently successful and Halsted, a fastidious and exacting surgeon, henceforth used them routinely. The practice spread rap-

idly to other American hospitals. Historians point out, however, that Halsted's interest in Carolyn Hampton, his operating room nurse, may have extended beyond her efficient hands. They were married in the following year. By the Spanish American War, U.S. army surgeons were routinely provided with gloves and by 1905 the operating hands of most western European surgeons and obstetricians were encased in reusable latex gloves. Disposable, single-use surgical gloves were introduced in the 1960s.

The glove, whether made of animal tissue or processed rubber, was promoted historically for a succession of medical reasons: first, as a carrier of lubricants to ease the movement of the examining hand without compromising tactile sensitivity; then, as a barrier to protect the examining physician from contagious diseases within the patient; and finally, as a means of protecting the patient by preventing the transfer of pathogenic agents from the hands of the physician to the patient's body.

Gloves had previously served a variety of purposes: for warmth, for stylish dress, for protection of the fingers in industry, for challenging others to a duel, and even as a surrogate for sensuous experience. [In the Capulet garden, Romeo whispers: "See! how she leans her cheek upon her hand; O! that I were a glove upon that hand, That I might touch that cheek."] But it required a trifling toy snatched from South American natives to provide the thermostable, flexible, thin and impervious membrane needed to create the surgical glove.

How many infections have been averted? How many lives have been saved by the introduction of surgeons' gloves? How many physicians sleep better in the knowledge that rubber gloves keep their hands from contaminating vulnerable patients? Perhaps they recall the psalmist's words: "He that hath clean hands and a pure heart" shall ascend the mountain of the Lord.

— Stanley M. Aronson, MD



Spinal Cord Injuries: Introduction

Guest Editors: J. Frederick Harrington, Jr., MD, and David Hamel, MPA

INTRODUCTION

Each year 55 Rhode Islanders are diagnosed with a spinal cord injury; and another 400 are admitted to hospitals with a suspicion of an injury. Most are young males, who, with proper care, can have long lives. Those lives can be meaningful, fulfilling, useful to the individual and to society, but that outcome is predicated on support from a range of people, including physicians, rehabilitation specialists, and peers.

Medical advances have resulted in higher survival rates and higher functional level for patients with spinal cord injury. Today's treatment protocols and techniques for spinal cord injury have marked progress. Dr. Kenneth Williams outlines the early treatment pathway, beginning at the scene of the injury and ending in the hospital emergency department, with key points to consider along the route. Drs. Khan, Kotechi, and Harrington elaborate on inpatient diagnosis and treatment - the acute management stage. They present a sample case discussion.

For spinal cord injury patients, "treatment" will inevitably include rehabilitation. Drs. Jon Mukand, Luba Karlin, and Susan Biener-Bergman discuss medical concerns dur-

ing rehabilitation, including treatment of sequelae. Rehabilitation, moreover, happens not just inside medical facilities, but at home, among family and friends. Susan Olson outlines the role that the government-funded Office of Rehabilitation Services can play in individuals' return to the workforce, and Judith Hammerlind Carlson describes TechAccess, a nonprofit organization that provides assistive technology to people with disabilities. Paul Choquette gives a client's perspective on recovery, which denotes a return to a full and productive life.

Physicians knowledgeable about spinal cord injury treatment can enhance patients' prognosis; physicians who are in addition knowledgeable about the multi-faceted process of rehabilitation can enhance patients' lives.

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Emergency Medical Services: Scene of Injury to Emergency Department – Key Issues for Spinal Cord Injuries

Kenneth A. Williams, MD, FACEP

PREHOSPITAL CARE

Suspect

In the prehospital environment, suspecting a spinal cord injury is the first and perhaps most important step in providing care. Vehicle crashes and falls account for about 70% of spinal cord injuries, with the remainder caused by sporting mishaps and interpersonal violence.¹ While young adult men are the most common victims, increased risk exists for those at extremes of age, patients with impaired coagulability, and patients with weakened skeletal structure due to metastatic disease, osteoporosis, steroid use, or other conditions. Therefore, heightened suspicion should be maintained for patients in these high-risk groups, even with minimal trauma. Victims

of trauma should be questioned about pain in the neck or back, abnormal sensation, such as burning, tingling or numbness, and about impaired motor function. Even without significant mechanism, the presence of any such symptom should trigger measures to protect the spine.

Stabilize

Stabilization of spinal cord injury patients consists of splinting the spine and beginning treatment to stabilize any concurrent conditions. Often these two goals conflict. For example, optimal spinal splinting includes careful application of various devices [collars, spine boards, extrication splints] without moving the pa-

Abbreviations Used:

CT	computed tomography
EMS	emergency medical service
MRI	magnetic resonance imaging
NHTSA	National Highway Traffic Safety Administration
SCI	spinal cord injury
SCIWRA	spinal cord injury without radiological evidence of abnormality

tient and then methodical repositioning into a position of supine spinal alignment on a padded, size-appropriate spine board with the head, torso, and lower extremities securely restrained to prevent movement. Even with these devices in place, an uncooperative patient can achieve signifi-

cant amounts of spine motion. The EMS professional must often continue manual stabilization and constant verbal reminders to achieve adequate splinting of the spine. Equipment for pediatric patients is now standard on all ambulances in Rhode Island.²

While this process can proceed in an orderly fashion when the patient is alert, otherwise uninjured, cooperative, and in an open environment [a soccer player lying on the field complaining of neck pain and arm tingling after "heading" the ball, for example], it must be balanced with the other stabilization needs of the patient in many trauma situations. Most victims of vehicle crashes have other potential or real injuries and are rarely found in position of supine spinal alignment. The EMS professional must weigh the need to obtain an airway, control hemorrhage, extricate the patient, and proceed with rapid transport to the hospital against the risks of moving a potentially unstable spine. In many situations, moderate efforts to control spinal motion [application of a rigid collar and head immobilization, rapid positioning on a firm board with straps] can be achieved while adequate attention is directed to airway control, intravenous access, and rapid transport.

Transport

An essential part of EMS care is transport to a hospital or other facility. In Rhode Island, the EMS destination is determined by patient preference, hospital availability, severity and type of injury, demographics, and patient condition.³ The EMS professional must select, sometimes in consultation with medical control, the best destination for each patient. During transport, stabilization must continue. This may mean selecting a route with smoother roads, driving more slowly, and in some cases using a helicopter to smoothly access the best destination facility.

Challenges during transport include maintaining calm rapport with the patient, who is now supine, strapped down, and probably in pain. Nausea and vomiting must be anticipated and suction ready. Other EMS

procedures, such as continued airway management, splinting and bandaging of other wounds, intravenous access, and monitoring, must also occur or continue during transport.

Early in transport, after essential patient care is completed, the EMS team notifies the receiving hospital via cellular telephone or radio. This begins the transfer of care to the emergency department team.

EMERGENCY DEPARTMENT MANAGEMENT

Continue Stabilization

When the patient arrives in the emergency department, it is imperative that the spine remain immobile while further evaluation and treatment occur. Through the use of several staff working together as a team, the patient can be moved onto the emergency department stretcher, evaluated and treated without risking further spinal injury. In almost every case, direct examination of the back is important. This can be accomplished through use of several coordinated people who roll the patient as a unit while the physician performs an examination of the back and any other necessary examination, such as auscultation of the posterior chest and a digital rectal examination to check tone and reflex status.

SUPPORT

Airway and Respiration

In cases of significant upper spinal cord injury or concurrent trauma to the head, neck, or thorax, prompt airway management and artificial ventilation may be necessary. Again, it is important to maintain stability during this procedure. Research suggests that orotracheal intubation can usually be accomplished successfully with careful stabilization of the head and neck.⁴ In most patients, sedatives and paralytics are indicated to prevent motion and reduce complications. In cases of significant anterior neck or facial trauma, other airway options, such as fiberoptic visualization or surgical approaches, may be indicated.

Blood Pressure

Patients who lose both neurologic function and autonomic tone below the level of a spinal cord injury are in a state of spinal shock. In addition to flaccid paralysis and loss of sensory input as well as deep tendon reflexes, these patients are often bradycardic and hypotensive. However, in the trauma patient, other causes of hypotension must be ruled out before a neurogenic cause is considered. Hypovolemia, tamponade, pneumothorax and other causes should be investigated and treated if found.

TREATMENT

Steroids

Varieties of pharmacologic agents have been investigated with the intent of improving outcome in spinal cord injury. The most promising treatment is methylprednisolone. Treatment with a bolus of 30 mg/kg and an infusion of 5.4 mg/kg/hr for the next 24 hours must be begun within 8 hours of injury to show neurologic improvement at six weeks and one year according to the National Acute Spinal Cord Injury Study.⁵

In many cases, spinal cord injury patients arrive in the emergency department hours after injury, and the decision to treat with steroids must be made promptly. The emergency care team should be prepared to institute therapy according to protocols arranged with consultants who will assume responsibility for patient care after the emergency department.

DIAGNOSE

Neurological Examination

Simultaneous with stabilization and indicated emergency treatment, the ER team should begin to determine the level and severity of a suspected spinal cord injury. The first step in this process is observation of the patient. External signs of trauma may provide a clue as to the mechanism of injury. Significant head injury may be associated with spinal injury. Axial loading injuries raise concern for instability of the upper cervical spine, while facial injuries suggest hyperflexion/hyperextension and therefore middle or lower

cervical injury. Chest and upper back contusions associated with shoulder belts suggest rotation or rotation/flexion of the thoracic spine. Abdominal seat belt injury suggests lumbar flexion, and lower extremity axial load injuries may produce compression of the lumbar spine.

Details about the mechanism of injury are also important. Bystanders and EMS professionals can often add significant information that clarifies the exact mechanism of injury and thereby improve the ability to localize the level of trauma. Their observations of the patient may be important as well. Motion, patterns of respiration, and specific complaints are all useful in determining patient condition and degree of injury. A rapid but detailed history and examination of proximal and distal motion in the extremities, notation of any areas of fasciculation, and any complaints of altered sensation should be obtained. Because various syndromes of complete and incomplete cord injury exist and may be diagnosed through knowledge of symptom details, it is best at an early stage to document the results of history and examination and presume an injury. A complete lesion below the cervical region will spare arm function and breathing, and incomplete lesions, such as central cord and anterior cord syndromes, may exhibit patterns of decreased motor and sensory function that change over time. Repeat examinations are therefore essential. Abdominal breathing suggests a lower cervical injury, and burning pain of the hands suggests a C6-7 injury.

Just as important as noting areas of decreased motion or sensation is a search for areas of spared function. For example, residual finger or toe motion, areas of spared sensation, and intact functions, such as rectal tone, may signal an incomplete injury and a markedly improved chance of functional recovery in a patient who appears otherwise to have a complete spinal cord lesion. Absence of the bulbocavernosus reflex, elicited by placing a finger in the patient's rectum and then tugging gently on the Foley catheter—an intact reflex results in a sharp distinct

rectal sphincter contraction—suggests spinal shock, and prognostic estimates cannot occur until the shock period is over, usually within 24 hours.

Stabilization of spinal cord injury patients consists of splinting the spine and beginning treatment to stabilize any concurrent conditions. Often these two goals conflict.



IMAGING

Plain radiography of the spine is indicated in patients with suggestive mechanism, symptoms, or signs of spinal cord injury. If the history is unobtainable or not reliable due to impaired cognition or distracting injury, cervical spine radiographs should be obtained. Most unstable injuries are visualized with standard 3-view cervical radiology protocols. Flexion-extension views, requiring only 10-15 degrees of active patient motion, can reveal ligamentous instability suggested by subtle plain radiographs. The SCIWRA syndrome, described as spinal cord injury without radiological evidence of abnormality in pediatric patients,⁶ confirms that there need to be no fracture or dislocation to have significant cord injury. Additional plain radiographic views, CT, or MRI should be obtained as indicated.

CONSULT

Consultation with orthopedic, neurosurgical, or other specialists in spine trauma should occur early in the ER evaluation. In some cases, consultation results in transfer from a referring institution, and the specialist can be present and awaiting patient arrival. In other cases, the emergency staff should consult promptly and prioritize care for the patient with an understanding of the needs of the arriving special-

ist. For example, a brief neurological examination prior to sedation and paralysis for airway control is possible in many cases and should be performed whenever possible. Protocols for advanced imaging, steroid treatment, and other management issues should be a cooperative effort among emergency and other specialty professionals.

NEW PROTOCOLS

Public Health and Prevention

The National Highway Traffic Safety Administration's EMS Agenda for the Future [released by NHTSA in 1996]⁷ broadens the goal of EMS systems from reduction in unnecessary death and disability to protecting the health of the community. Improvement in the quality of EMS care is now linked to overall community health, but the EMS system remains the public's emergency medical safety net. Since spinal cord injury is frequently related to trauma, the chance for improvement in the community health is significant. This is a situation where EMS professionals can take a leadership role in training the public about safety. Public lectures and demonstrations about bicycle, sporting, and driving safety are ideal forums for EMS and emergency care professionals to help prevent spinal cord injury.

Preventing Secondary Spinal Cord Injury

Although significant injury can certainly produce devastating spinal cord trauma, research suggests that the maximum neurologic deficit does not occur instantaneously in many cases. Similar to free radical-induced lipid peroxidation reaction research on resuscitation and stroke, research on a spinal cord injury may produce medications and other treatments that can minimize the effects of trauma on the spinal cord. While not currently offered as standard therapy, some of these treatments show promise subject to further research.

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Acute Management of Patients with Spinal Cord Injury

Ahmed M. Khan MD, Nilesch Kotecha MD, J. Frederick Harrington, Jr., MD

Successful acute management of patients with spinal cord injury (SCI) requires a team effort with pre-hospital personnel, emergency physicians, trauma surgeons, and spine surgeons. This review will focus on pre-hospital management, resuscitation, diagnosis and treatment of SCI.

The epidemiology of SCI shows young males to constitute the majority of victims. The cervical spine is the most commonly injured area (42% of all spine injuries) followed by the thoracic (31%) and lumbar (27%) segments.² Adults account for the majority of SCI with only 5% occurring in the pediatric population.

PRE-HOSPITAL MANAGEMENT

The treatment of patients with SCI, as with any trauma patient, begins with pre-hospital management. Any person suffering a significant trauma, loss of consciousness, or complaining of pain in the spine or extremity weakness or numbness should be suspected of having SCI and thus handled with precaution. Immobilization of the spine should be applied

prior to and during extrication when possible. A rigid cervical collar should be placed snugly around the neck. Log roll technique should be used when moving the patient. The patient should be positioned on a spine board with the head sandwiched between sandbags and strapped to the board.

Abbreviations Used:

ABC	airway, breathing, circulation
ASIA	American Spinal Injury Association
ATLS	Advanced Trauma and Life Support
ER	emergency room
SCI	spinal cord injury

STANDARD NEUROLOGICAL CLASSIFICATION OF SPINAL CORD INJURY

MOTOR
KEY MUSCLES

C3	Elbow flexors
C4	Wrist extensors
C5	Elbow flexors
C6	Finger flexors (distal phalanx of middle finger)
C7	Finger abductors (little finger)
T1	
T2	
T3	
T4	
T5	
T6	
T7	
T8	
T9	
T10	
T11	
T12	
L1	Hip flexors
L2	Knee extensors
L3	Ankle dorsiflexors
L4	Leg toe extensors
L5	Ankle plantar flexors
S1	
S2	
S3	
S4	
S5	

0 = total paralysis
1 = palpable or visible contraction
2 = active movement, gravity eliminated
3 = active movement, against gravity
4 = active movement, against some resistance
5 = active movement, against full resistance
NT = not testable

Voluntary anal contraction (Yes/No)

TOTALS
(MAXIMUM) (50) (50) (100)

MOTOR SCORE

SENSORY
KEY SENSORY POINTS

C3	
C4	
C5	
C6	
C7	
C8	
T1	
T2	
T3	
T4	
T5	
T6	
T7	
T8	
T9	
T10	
T11	
T12	
L1	
L2	
L3	
L4	
L5	
S1	
S2	
S3	
S4	
S5	

0 = absent
1 = impaired
2 = normal
NT = not testable

Any anal sensation (Yes/No)

TOTALS
(MAXIMUM) (56) (56) (56) (56)

PIN PRICK SCORE (max: 112)
LIGHT TOUCH SCORE (max: 112)

NEUROLOGICAL LEVEL
The most caudal segment with normal function

COMPLETE OR INCOMPLETE?
Incomplete = presence of any sensory or motor function in lowest sacral segment

ZONE OF PARTIAL PRESERVATION
Partially innervated segments

SENSORY R L
MOTOR R L

This form may be copied freely but should not be altered without permission from the American Spinal Injury Association

Fig. 1. American Spinal Injury Association (ASIA) motor and sensory scoring system for classification of spinal cord injury.

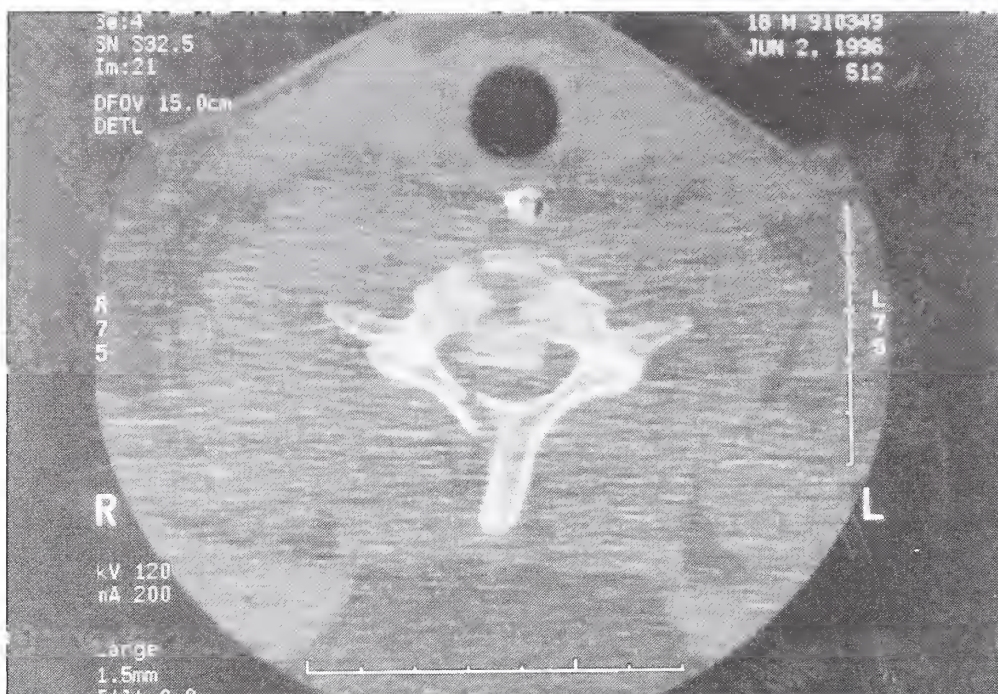


Fig. 2. Axial CT image of C7 body showing burst fracture with retropulsed fragment and significant spinal canal compromise.

RESUSCITATION AND DIAGNOSIS

Regional trauma centers with expertise in managing patients with SCI offer the best hope for these patients, because frequently decisions must be made rapidly by multiple specialty providers. As patients with SCI arrive at the ER, initial management should proceed according to the American College of Surgeons Advanced Trauma and Life



Fig. 3. (a) Sagittal and (b) axial T2-weighted MRI showing retropulsed segment at C7 with cord compression.

Support (ATLS) guidelines with attention to the ABCs (airway, breathing, circulation). Patients with cervical injury at or above C5 may have diminished respiratory function due to diaphragmatic paralysis and require intubation. If necessary, intubation should be performed with the neck held in neutral alignment avoiding hyperextension. If intubation cannot be performed orotracheally, then it must be attempted nasotracheally.

Patients with cervical or high thoracic injury may present in neurogenic shock characterized by hypotension and bradycardia because adrenergic reflex arcs have been interrupted. Autonomic dysfunction may be evident by priapism. Palpation of the spine for step-off or for tenderness should be performed. Although other etiologies

of hypotension need to be evaluated in trauma patients, neurogenic shock can be treated effectively with fluids along with insertion of a central venous catheter to ensure that the patient is not over-hydrated, since normal physiological responses to over-hydration may be muted.³ Once euvolemia is obtained, vasopressors can be used to keep blood pressure at 100-120 systolic, with dopamine considered the vasopressor of choice. Experimental investigations suggest that keeping perfusion pressures between 70 and 80 during resuscitation may improve outcome without increased risk for hemorrhage into the spinal cord.

Patients with neurological deficits and suspected SCI should be started on high-dose methylprednisolone (Solu-Medrol®) as soon as possible but only within 8 hours of the injury. This consists of a single bolus dose of 30 mg/kg over 15 minutes followed by a continuous infusion 45 minutes after the bolus of 5.4 mg/kg/hr for 23 hours if started within the first 3 hours after injury and for 48 hours if started 3-8 hours after injury. Beyond 8 hours, methylprednisolone is of no apparent benefit. Methylprednisolone has been shown to have beneficial effects in both complete and incomplete injuries at 6-week, 6-month, and 1-year follow-up.²

The physical examination of patients with SCI should focus on motor and sensory levels of injury (i.e. C5, T6, etc.). It is particularly important to document a complete baseline spinal cord examination on admission so that improvements and deterioration can be accurately monitored. The American Spinal Injury Association (ASIA) examination should be used for best results. (Figure 1) Components include measurements of strength on a 0-5 scale with zero representing paralysis and 5, normal strength in all upper and lower extremity motor groups, and sensory examination which includes pinprick and light touch sensation on all dermatomes from C2 to S5.¹

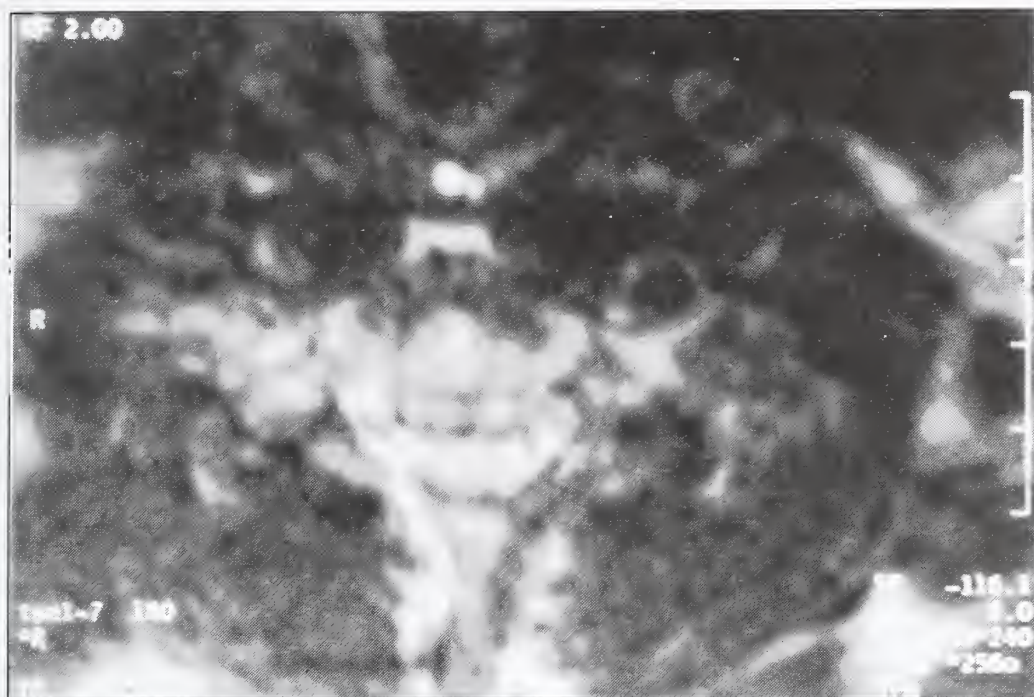


Fig. 4. Lateral C-spine radiograph showing anterior fusion of C6 to T1 with an anterior cervical plate and screws.

Prognosis greatly depends on whether the patient has a complete paraplegia (no motor or sensory function below the level of injury). Patients with complete injury have a grim prognosis for functionally significant improvement. However, if some basic reflexes, such as the bulbocavernosus

reflex, are present, even in the absence of motor function, prognosis is improved.⁸

Radiological evaluation of the patient should contain complete cervical, thoracic, and lumbar films, as patients with a spine fracture may have a 20% incidence of another spine fracture.⁶

Any fracture or subluxation seen on C-spine x-rays requires a CT through the entire cervical spine to pick up undetected second fractures. A complete cervical examination should include adequate visualization of the odontoid either through plain radiographs or computed tomography (CT), an AP film, and a lateral radiograph to T1. If C7-T1 cannot be visualized despite a "swimmer's view" radiograph, then a CT should be performed to visualize this area. AP and lateral radiographs of the thoracic and lumbar spine should be performed. If there is an upper rib or mediastinal injury, then CT should be obtained from T1-T6 to rule out a fracture in this region which is less well visualized by plain x-rays. CT is the most sensitive imaging modality for spinal fractures. (Figure 2) Magnetic resonance imaging is performed on all cervical injuries (Figure 3) and on many thoracic and lumbar injuries to define patterns of ligamentous injury and hematomyelia but, most importantly, to rule out the presence of compressive disc material which is

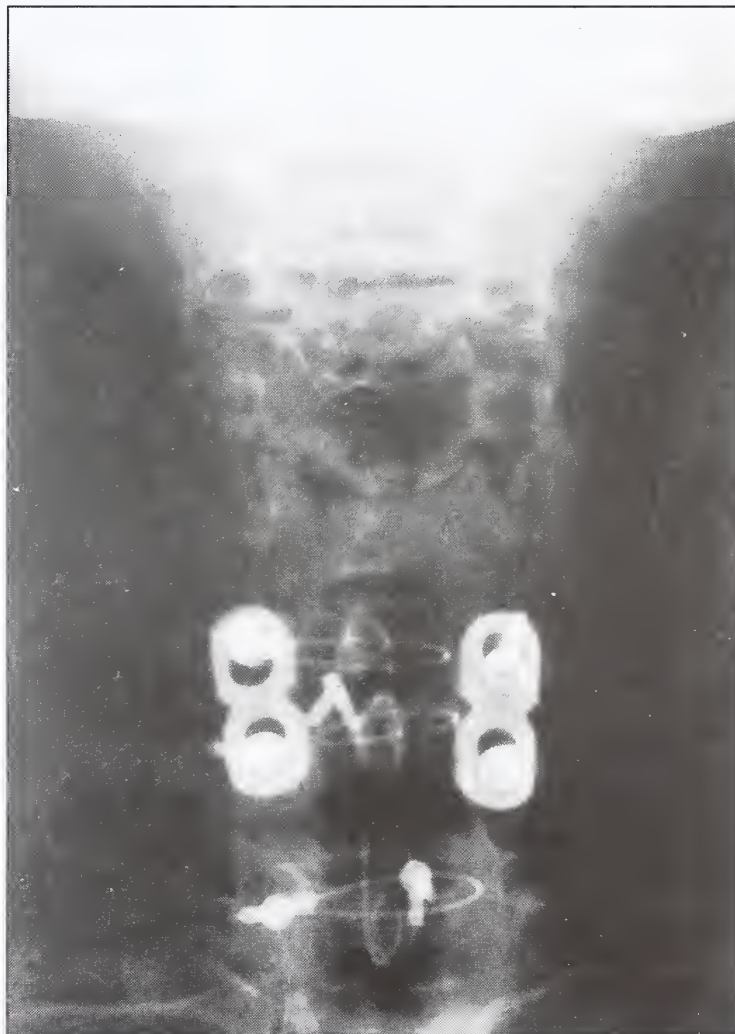


Fig. 5. Postoperative (a) lateral and (b) AP C-spine radiograph showing lateral mass screws and posterior plate at C6 and C7 with interspinous process wiring.

present in up to 30% of cervical fractures.⁴

TREATMENT

Cervical injuries with significant subluxation can often be reduced by HALO traction. We believe that internal surgical stabilization leads to more reliable fusion in most cervical spine injuries. In the thoracic and lumbar spine, nonsurgical treatment is often successful. In cases of spinal cord compression or when reduction cannot be achieved, then patients must be taken urgently for surgical reduction. This requires a posterior approach in most cases, then decompression, and stabilization. Decompression may be performed posteriorly through a laminectomy and anteriorly through a vertebrectomy.

Once adequate decompression and reduction have been performed, various stabilization techniques can be employed to artificially stabilize the spine, including titanium plates and screws to bridge the fracture across the vertebral bodies anteriorly. (Figure 4) Posteriorly, pedicle screws or lateral mass plates and screws bridge the gap in the facet joints. (Figure 5) Sublaminar wires and rods can hold multiple spinal segments firmly when the laminae are intact. Without the use of additional bone substrate, most instrumented fusions would weaken within a matter of weeks. All fusions require bone scraping and bone grafts to obtain stable long-term fusion.

Patients with dense paraplegia or quadriplegia are at high risk for deep

Radiological evaluation of the patient should contain complete cervical, thoracic, and lumbar films, as patients with a spine fracture have a 20% incidence of another spine fracture.



venous thrombosis and pulmonary emboli.⁷ We favor the use of prophylactic vena cava filters with aspirin as prophylaxis against pulmonary embolism, although subcutaneous heparin with frequent Doppler studies may be an alternative. Finally, patients with residual functional deficits will require extensive rehabilitation. The surgeon needs to make sure fusion is achieved and that patients are observed for syrinx development over the next several years. Physiatrists and internists are essential to assure maintenance of functional capacity and to monitor the patient for distress related to decubiti, respiratory or genitourinary difficulties. Long-term survival is maximized by meticulous attention to the problems these patients have with maintenance of their respiratory and genitourinary systems.

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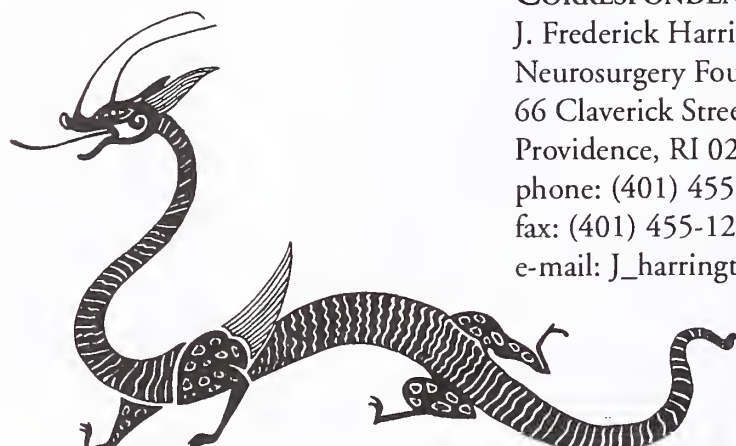
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Rehabilitation and Wellness After Spinal Cord Injury

Jon Mukand, MD, PhD, Luba Karlin, MD, Susan Biener-Bergman, MD

Medicine has made significant progress in improving the medical management and quality of life of persons with spinal cord injury (SCI).¹ Ideally, persons with SCI should be empowered to assume responsibility for their physical, psychological, and social well-being. This review describes the management of SCI complications in the pulmonary, cardiovascular, genitourinary, gastrointestinal, integumentary, and metabolic systems.

PULMONARY

Lung complications are a major cause of morbidity and mortality in both the acute and chronic phases after the injury.² With paraplegia from T1 through T12, a progressive loss of abdominal and intercostal motor function impairs breathing and coughing. Patients with C4 through C8 quadriplegia have no intercostal or abdominal muscle activity, resulting in an ineffective cough mechanism. Injuries at the C4 and C5 levels allow partial diaphragmatic function, but at C3 the patient requires ventilatory support.

The acute management of pulmonary function includes treating hypoxia through adequate ventilation; minimizing atelectasis and aspiration to avoid pneumonia; and aggressive pulmonary toilette to compensate for the impaired clearing of secretions. Almost all patients with injuries at or above C3 require long-term assisted ventilation; so tracheostomy should be performed early to avoid complications of prolonged intubation, such as subglottic and tracheal stenosis.³

Alternative methods of respiratory management include intermittent positive pressure ventilation (IPPV), rocking beds, glossopharyngeal breathing, noninvasive intermittent positive pressure ventilation, and electrophrenic pacing. Recent literature suggests an improved quality of life with noninvasive methods as opposed to tra-

cheostomy.^{4,5,6}

To prevent pulmonary complications, annual follow-up includes measurements of vital capacity and periodic chest x-rays and blood gases. Pneumovax and flu vaccine are important preventive measures. Patients and caregivers should be educated about techniques to clear secretions and prevent atelectasis, mucus plugs, and pneumonia. Incentive spirometry is a beneficial exercise and gives an early indication of complications if the maximal inspired volume declines.¹

CARDIOVASCULAR

Cardiovascular problems in patients with SCI depend on age, premorbid cardiovascular disease, the level of the neurologic lesion, and complications of immobilization. Thromboembolism is a life-threatening complication and deep venous thrombosis (DVT) occurs in about 80% of patients.¹ Prophylaxis includes heparin or low molecular-weight heparin, intermittent pneumatic compression boots, and thigh-high elastic stockings.

Clinical monitoring is important, but many of the usual criteria are absent. Calf tenderness is unreliable in the insensate patient, but thigh and calf size as well as edema can be helpful indicators. Impedance plethysmography and duplex scanning are effective in detecting thigh clots, but are less helpful in calf disease.^{1,7} If there is any doubt, venography should be done. Some facilities now have magnetic resonance venography, which allows noninvasive testing.

After treatment with anticoagulation, gradual mobilization helps prevent bleeding, especially in patients with severe spasticity who have vigorous stretching exercises. With an inferior vena cava filter, assisted cough maneuvers for clearing secretions

Abbreviations Used:

AD	autonomic dysreflexia
DVT	deep venous thrombosis
GI	gastrointestinal
HO	heterotopic ossification
ICP	intermittent catheterization program
IPPV	intermittent positive pressure ventilation
NSAID	nonsteroidal anti-inflammatory medication
SCI	spinal cord injury
UTI	urinary tract infection

should be done only when absolutely necessary due to the risk of dislodging the filter.¹

Cardiac disease is the primary cause of death in 18.7% of all patients and a contributing factor in 22.4% of individuals followed up to six years after the original injury.⁸ The diagnosis of cardiac disease in individuals with SCI is challenging because of absent, subtle, or atypical clinical presentations, such as referred pain in areas not affected by the injury.⁹ A thallium scan with upper extremity exercise, if possible, may assist in the diagnosis of silent ischemia. A high index of suspicion is helpful in detecting cardiac disease in this population.

Neurogenic orthostatic hypotension is associated with lightheadedness, dizziness, blurry vision, weakness, or even syncope. In SCI autonomic reflexes through baroreceptors are lost when the lesion is above T6. As spasticity develops, postural changes are less of a problem because of involuntary muscle activity, but some patients have long-term orthostatic hypotension.

Prior to mobilization, the blood pressure and pulse should be obtained in the supine and sitting positions. Elastic compression stockings, an abdominal binder, adequate hydration, and gradual changes in position may be effective. In refractory cases, medications and salt loading may be neces-

sary.¹ Midodrine is a peripheral alpha-adrenergic agonist that increases upright blood pressure and improves the symptoms of orthostasis (unpublished data). The risk of supine hypertension with midodrine (25% of patients) can be reduced by taking the final daily dose at least four hours before bedtime.^{12,13}

Autonomic dysreflexia (AD) is an acute hypertensive syndrome that occurs in SCI at T6 or above. It is often precipitated by bladder distention, fecal impaction, or other noxious stimuli below the level of the SCI. Other causes of AD include UTI, bladder or kidney stones, cystoscopy, gallstones, peptic ulcer disease, hemorrhoids, sexual intercourse, DVT, pressure ulcers, ingrown toenails, fractures.¹⁴ Pain impulses ascend in the spinothalamic tract in addition to stimulating sympathetic neurons. Relatively unopposed sympathetic outflow below T6 releases neurotransmitters, such as norepinephrine. Sympathetic inhibitory outflow from the vasomotor centers above the SCI cannot pass below the lesion, causing profuse sweating, vasodilation, and skin flushing above the level of the injury.

Prompt treatment is necessary to prevent intracranial hemorrhage. The patient is placed upright to reduce the blood pressure. The blood pressure and pulse should be monitored frequently (every 2 to 5 minutes) because of rapid fluctuations. Instigating causes should be determined and treated. Lidocaine gel should be used during any bladder and bowel manipulations to minimize further noxious afferent input. If the blood pressure remains high, antihypertensive agents with rapid onset and short duration are used while the causes of AD are being investigated. Nitropaste is rapid in onset and is easily removed if the pressure goes too low. Nifedipine, hydralazine, and diazoxide may also be used to treat this condition.^{14,15} Unfortunately, there are no comparative studies on the best agent.

GENITOURINARY

A major problem after SCI is the loss of normal genitourinary function. Historically, renal failure has been the

major cause of death in persons with SCI, but with the advances in urologic management, it is now the fourth leading cause of death.^{1,20} Urinary incontinence causes skin maceration, predisposing to decubitus ulcers. Complications of indwelling catheters include renal and bladder calculi, malignancy, scrotal abscess, fistulas, urethral ulceration. Bladder dysfunction also has significant social consequences causing embarrassment, depression, economic costs, and dependence on family members or health care workers.

Bladder dysfunction is closely related to the level of the injury. Lesions to the peripheral innervation or the sacral center result in a lower motor neuron disorder causing a hypotonic detrusor and/or sphincter, urinary retention, and overflow incontinence. Injuries above the sacral micturition center result in an upper motor neuron bladder; the detrusor is hyperreflexic causing low urinary volumes, high bladder pressures, and diminished bladder compliance. Most patients will have some incontinence and develop detrusor sphincter dyssynergia which results in incomplete emptying of the bladder. Repeated UTIs and vesicoureteral reflux cause scarring and loss of renal function.

In the upper motor neuron bladder, a urodynamics study is helpful. Anticholinergic medications reduce detrusor tone, allowing greater bladder capacity and decreasing vesicoureteral reflux. Patients will benefit from a combination of anticholinergic medications with intermittent catheterization or an indwelling catheter, preferably a suprapubic tube. If internal sphincter tone is excessive, alpha-adrenergic blockers, such as prazosin, may decrease outlet obstruction. External sphincter tone may be reduced with medications, such as Baclofen® and Dantrium®.²¹ In males, an alternative strategy is sphincterotomy combined with a condom catheter, but side effects include persistent bleeding and loss of erectile function. On rare occasions, bladder augmentation with a piece of small bowel can increase bladder capacity, allowing an intermittent catheterization program. A competent

sphincter is required for this strategy. Another surgical option is to divert urine flow to the abdominal wall by creating a conduit with a portion of the ileal loop.

Lower motor neuron bladder dysfunction may present with two clinical situations. In the first one, sphincter tone is diminished and detrusor tone is normal or compromised. This results in continuous incontinence which is usually managed with an indwelling condom catheter for males. Sphincter tone can be increased with alpha-adrenergic medications like Midodrine®, but this is unlikely to result in full continence. In selected cases, an artificial sphincter may be the solution. In the second clinical situation, the sphincter maintains continence, but detrusor tone is diminished, and the patient cannot void. In this scenario, an intermittent catheterization program (ICP) is effective. An alternative is bladder evacuation with the Valsalva maneuver or suprapubic pressure. An indwelling catheter is used as a last resort. Cholinergic agonists, such as Urecholine®, are usually ineffective in increasing detrusor tone, but a trial may be warranted.^{1,20}

GASTROINTESTINAL

GI problems include constipation, ileus, impaction, gastric ulcers, gastroesophageal reflux, nausea, appetite loss, and incontinence. Unidentified GI complications may account for 5% to 10% of deaths associated with SCI, and 11% of hospitalized patients had serious GI complications.¹⁶ These problems were more frequent among patients with cervical and upper thoracic injuries than with lower lesions.

An injury above the sacral segments of the spinal cord produces a hyperreflexic or upper motor neuron bowel; spasticity of the pelvic floor and the loss of descending inhibition prevent sphincter relaxation and promote stool retention. Fortunately, nerve connections between the spinal cord and colon remain intact, allowing reflex stool propulsion.¹⁶ A complete injury at the sacral segments (cauda equina syndrome) results in a hyporeflexic (lower motor neuron) bowel with no

reflex peristalsis. This results in hypomotility and fecal incontinence due to a hypotonic anal sphincter.

Bowel programs should start during the acute phase and continue throughout life. Differences in programs for hyper and hyporeflexic bowels include the type of rectal stimulant, medications, and frequency of bowel care. In either program, bowel care should be scheduled at the same time of day for a habitual and predictable response. Ingestion of food or liquids 30 minutes before bowel care may stimulate the gastrocolic response. Bowel care should be scheduled at least every other day to avoid colorectal distention.

Bowel care for the hyperreflexic bowel consists of placing a chemical stimulant onto the rectal mucosa, assuming an upright or side-lying position, digital stimulation, and other assisted techniques, such as abdominal massage, deep breathing, or the Valsalva maneuver. Routine care for the hyporeflexic bowel should be done in the upright or side-lying position with gentle Valsalva maneuvers and manual evacuation of stool.

Diet, fluids, and regular activity help modulate stool consistency. The goal for hyperreflexic bowels is soft stool that can be readily evacuated with rectal stimulation. In the hyporeflexic bowel, formed stool promotes both continence and easy manual evacuation. A diet with about 15 grams of fiber per day is ideal but may require titration.¹⁶ Fluid intake should promote optimal stool consistency as well as bladder management. Suppositories or digital stimulation may cause AD, so the least noxious stimulus should be used, sometimes with lidocaine gel.

The medical management of chronic constipation includes the gradual use of laxative agents, such as lubricants, osmotics, and cathartics. Cisapride® is an indirect cholinergic stimulant that is quite effective (unpublished data). Cholinergic agonists, such as Urecholine®, improve ileus, but their use is limited by side effects. Dopamine antagonists have a prokinetic effect in the proximal GI tract. Metoclopramide, a cholinergic

agonist and dopamine antagonist, has been used to promote gastric emptying, but it causes diarrhea, vomiting, and extrapyramidal effects.¹⁶

Surgical intervention is a difficult decision for the individual, the family, and the physician. Surgery usually involves a permanent stoma. Indications include recurrent pressure ulcers, hemorrhoidal bleeding, and chronic infections.¹⁶ A gastric emptying scan may assist in determining the type of surgical procedure (unpublished data).

Historically, renal failure has been the major cause of death in persons with SCI, but with the advances in urologic management, it is now the fourth leading cause of death.



INTEGUMENTARY

Decubitus ulcers are a major complication of SCI, affecting about 25% of patients.¹⁷ Predisposing factors are pressure, shear forces, age, edema, altered sensation, neurotrophic changes, and psychological problems.¹ Additional factors in ulcer formation include heterotopic ossification, anemia, spasticity, and malnutrition.

Ulcer prevention requires frequent weight shifts for reperfusion of ischemic areas. During initial immobilization in a wheelchair, weight shift should be done every 15 minutes and skin checks every 1 to 2 hours. With more activity, shifting can be less frequent because of skin adaptation.

Numerous beds and mattress materials have been developed to distribute forces away from bony prominences and over a larger area. Air and water beds are excellent for these purposes, but transferring patients in and out of them is difficult. Wheelchair cushions are designed for opti-

mal weight distribution, sitting position, and durability. Dimensions of the compressed cushion affect various wheelchair parameters including the backrest, armrest, and seat height. The choice of cushion materials (air, foam, gel) involves issues such as sensory function, pressure distribution, spasticity, and incontinence.^{1,17,18}

The essential decision in treating decubitus ulcers is whether to pursue conservative or operative management. Both approaches require that the wound have no pressure until the skin is completely healed. Factors that have contributed to the ulcer should be identified and avoided. The most important principles of wound care are cleansing, debridement, and a moist environment—for optimal cellular mitosis. Wet-to-dry dressings help debride necrotic wounds and wet-to-moist dressings maintain a clean, moist wound bed. These dressings are changed every 6-8 hours, increasing the costs of dressing materials and nursing care. Newer dressings (transparent membranes, hydrocolloids, hydrogels, and foam) can be changed once a day or less frequently. They differ in oxygen permeability, absorption, adherence to the wound, need for secondary dressings, and patient comfort.¹⁸

If surgery is necessary, a plan for current and future management should consider the probability of additional skin problems and surgical procedures. Myocutaneous flaps are based on the principle of minimizing dead space. They provide well-vascularized tissue to fill the large dead space after pressure ulcer resection to maintain tissue integrity.^{17,18} Surgery should not be attempted unless protein stores are adequate.

METABOLIC

Heterotopic ossification (HO) refers to ectopic bone formation in periarticular soft tissues. HO usually occurs in the first several months, below the level of injury, in about 29% of patients.¹⁹ Risk factors include spasticity, immobilization, and long bone fractures. Physical findings are pain, decreased range of motion, swelling, increased local temperature, fever, and

erythema. The hip is the most common site.^{1,19} Complications from HO include joint contracture and ankylosis, vascular compression, and lymphedema. The triple-phase bone scan can reveal ectopic ossification even before radiographs are positive. Serum alkaline phosphatase and phosphorus levels may be elevated but are of limited diagnostic use.^{1,19}

Prophylactic measures include range of motion exercises, spasticity management, Didronel, and nonsteroidal anti-inflammatory medication (NSAIDs). Didronel inhibits the transformation of calcium phosphate into crystalline hydroxyapatite, but it does not affect the bone matrix formation that is the initial phase of ectopic ossification. Didronel appears to decrease the incidence and severity of HO after SCI.¹ The side effects of Didronel include nausea, vomiting, and diarrhea; osteomalacia and long bone fractures may occur after more than six months of treatment. These patients are already at increased risk of osteoporosis, immobilization hypercalcemia, and fractures. NSAIDs probably suppress heterotopic bone by inhibiting prostaglandin synthesis and the inflammatory reaction that induces ectopic bone. Potential contraindications include peptic ulcer disease and dysfunction of the renal and hepatic systems. Once HO is established, pharmacological treatment is not effective. At that point, options include joint manipulation under anesthesia or surgical resection combined with radiation therapy and NSAIDs.^{1,19}

CONCLUSION

Persons with SCI have a variety of unusual medical and surgical complications. These require close monitoring in the acute and neurorehabilitation settings, where specialized staff provide intensive rehabilitation for the numerous disabilities associated with SCI. In addition, long-term management of these complications will help patients achieve optimal wellness.

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The Public Vocational Rehabilitation Program

A Resource for Individuals with Spinal Cord Injury

Susan Olson, MEd

A dive, a leap into the surf, a vehicle accident, a gun shot: In an instant a life, often a young life, is transformed forever. The person's understanding of the transformation is an individual process, building through acute care, inpatient rehabilitation, and the return to home, community, and work.

What are some of the changes experienced by the individual? Height has most likely been reduced (wheelchair users have lost almost half their height). S/he moves differently, rolling rather than walking. If s/he has little or no use of arms, the wheelchair will be motorized, with a mouth- or chin-activated lever.

The average home is probably not equipped for entrance, egress or moving from room to room. S/he cannot independently use the bathroom or kitchen or move around rooms smoothly. A ramp or a lift is probably necessary. Doors need to be widened, rugs removed, bathrooms and kitchens remodeled. An Environmental Control Unit may be necessary to operate lights, TV, and the CD player. S/he may need to learn new skills for self-care and may need to instruct a Personal Care Assistant (PCA) to assist with personal care.

A car will need to be adapted with hand controls (if s/he has use of upper limbs); or if s/he uses a motorized chair, s/he will need a specially-adapted van.

These are some tangible changes.

Essential intangible changes will require the person to reframe his or her identity as a woman, man, student, family and community member, and worker.

RETURNING OR GOING TO WORK

The individual as "worker" is the focus of the state/ federal vocational rehabilitation program. All of the above, however, may be integral components of vocational rehabilitation because in order to work an individual must be able to bathe, dress, leave home, and commute to the job. In ad-

dition, if s/he worked before the injury, the job needs to be "accommodated" to meet the individual's needs in the workplace. Accommodations may include raising a desk for a chair to fit under, adapting computer and mouse for operation, purchasing voice-activated software, and re-arranging the office. And if s/he or he has not yet started a job or a career path, or needs to change direction due to the spinal cord injury, a vocational rehabilitation counselor is an important resource and partner.

The vocational rehabilitation program in Rhode Island, administered by the Office of Rehabilitation Services within the Department of Human Services, has helped many individuals reach their career goals. Recently, six individuals with spinal cord injuries obtained the following jobs: Business Manager, Financial Advisor, Computer-Aided Draftsman, Broadcaster, Journalist, Clerical Worker. Most individuals received low and high tech assistive technology (reachers, dressing sticks, zipper pullers, phone holders, key holders, tub bench, ramp and or stair glide). Rehabilitation Technologists contracted by ORS assist in identifying assistive technology solutions. Each client received counseling and guidance related to vocational direction and training and financial assistance toward training. When in a training program, the Rehabilitation Counselor and Rehabilitation Technologist worked with the college or training facility to identify accommodations required. Several clients received services to modify their homes. In each situation the Vocational Rehabilitation Counselor provided or coordinated job placement services.

APPLYING FOR VOCATIONAL REHABILITATION SERVICES

Any individual may contact ORS through its home page: <http://www.ors.state.ri.us>, by phone, or letter (see below) to obtain information or an application. ORS Counselors are

Abbreviations Used:

CD	compact disk
ORS	Office of Rehabilitation Services
PCA	personal care assistant

also available at the netWORKri (One Stop Career Center) offices from 8:30 to 4:00, Monday through Friday.

ELIGIBILITY, EMPLOYMENT PLAN, AND SERVICES

Although an eligibility determination is necessary before services can be provided, most individuals with spinal cord injury who want to become employed will be eligible for services. The individual with the disability chooses the vocational direction and services with assistance from the ORS Counselor. The types of assistance and services that can be provided, in addition to vocational rehabilitation counseling and guidance, may include vocational testing, rehabilitation technology assessments and assistive technology, driving evaluation and training, independent living assessments, physical and mental restoration services related to employment, job preparation and placement services.

Services that are identified in the Individualized Plan for Employment that have no needs test include Counseling and Guidance, Rehabilitation Technology Assessment, Vocational Evaluations, and Job Placement. Some services such as purchase of training, equipment, Personal Assistance, or therapy, may require financial participation from the individual depending on his/her income.

ORS services are geared to help the client achieve a vocational goal. An outcome is considered successful when s/he has held a job for at least 90 days and is satisfied with the job. At this point the file is closed; however, some services can be provided afterward; e.g., another rehabilitation technology assessment because the job or technology changes.

In the past five years, the Office

of Rehabilitation Services assisted an average of 90 individuals yearly who have spinal cord injury. More than 25% of them are coded as having impairments of 3 or more limbs. In the past five years 48 individuals reached successful outcomes. It is common for a person with significant disability to be involved with ORS services for several years before reaching an employment goal with no further vocational rehabilitation services required. Each plan and outcome is individually determined.

Susan Olson, MEd, is Deputy Administrator, Office of Rehabilitation Services.

FOR MORE INFORMATION about Vocational Rehabilitation Services, Services for the Blind and Visually Impaired, Independent Living Services and/or Assistive Technology:

Office of Rehabilitation Services

40 Fountain Street, Providence, RI 02903

phone: (800) 752-8088

(401) 421-7005, (401) 421-7016 (TDD)

(401) 272-8090 (Spanish), (401) 272-7990 (Cambodian)

fax: (401) 421-9259

<http://www.ors.state.ri.us>

I & R for General Questions about Assistive Technology:

phone: (800) 916-8324 In-state

(401) 463-0202 (V/TDD).

<http://www.atap.state.ri.us>

Assistive Technology for People with Spinal Cord Injuries: What Physicians Need to Know

Judith Hammerlind Carlson, MS, CCC-SLP

Although improvements in medical care promise a better neurological outcome, most patients with spinal cord injury have persistent neurological deficits. Traditional items, such as braces and wheelchairs, help improve function. However, in our technologically-advanced world, it is possible for spinal cord-injured patients to benefit from more modern devices, or "assistive technologies." We are hoping to increase awareness of some of the amazing products that help the lives of spinal cord injured patients - products which may be as helpful as either medicines or surgery.

WHAT IS ASSISTIVE TECHNOLOGY?

Assistive technology is any item, piece of equipment or product system whether acquired commercially off the shelf, modified, or customized that is used to increase or improve the functional capabilities of a person with a disability. This broad definition emphasizes improving functional capability and includes a wide range of devices from simple items such as "reachers" to help a person pick up an object from the floor to more sophisticated products such as "voice-activated computers" that provide opportunities for employment and independent living.

HOW CAN ASSISTIVE TECHNOLOGY BENEFIT PERSONS WITH SPINAL CORD INJURIES?

Appropriately selected assistive technologies can significantly impact on a spinal cord patient's functional capabilities.

- * Mobility - devices such as power chairs, vehicle adaptations, sport wheelchairs, scooters, etc. enable people to move more freely and independently.
- * Independent living - devices such as hands-free telephones, remote controlled lights and doors, emergency call systems, barrier-free home modifications, etc. enable people to maximize control of their own environments.

- * Communication - devices such as adapted computer systems using switches, modified keyboards, voice activation, etc. enable people to use computers to access standard software for word processing, e-mail, faxing, banking, stock transactions, shopping, surfing the internet, etc.
- * Recreation - equipment adaptations for sports such as tennis, skiing, target shooting, and sailing, as well as adaptations for cameras, gardening, reading, etc. enable people to participate and enjoy leisure time.
- * Employment - electric doors, ramps, workstation modifications, and accessible computers and office equipment make it possible for persons to return to work or establish new careers.

WHO IDENTIFIES APPROPRIATE ASSISTIVE TECHNOLOGY?

Identifying appropriate assistive technology is a team decision involving the patient, his/her family, the physician, occupational therapists, physical therapists, speech-language pathologists, rehabilitation engineers, equipment vendors and others as needed. As there is currently no mandatory licensure or certification in the field of assistive technology, care must be taken when referring patients to assistive technology specialists to insure that the specialist has the expertise and experience necessary to help the patient and the team make an informed decision.

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Accessing Medical Care With a Spinal Cord Injury

Paul A. Choquette

The most important thing to consider when a person with a spinal cord injury attempts to access health care is not whether there is an office ramp for the person's wheelchair, but whether there is access to information that will help this person accept and live his/her life with the injury.

As medical and rehabilitative technology has advanced over the years, so too have the attitudes of medical practitioners when treating an individual with a spinal cord injury. The role of the medical provider is not as much to "fix" the person, but to enhance that person's ability to live through the injury and still maximize his/her independence and achieve whatever goals s/he may set. The physician's role, and the individual's, changes over time, from one of doctor/patient to one of advisor/implementer. As these roles change so do the needs of the individual for medical care. Where once the patient needed treatment of acute medical problems and complications resulting from a major nervous system injury, the patient now needs maintenance therapies and monitoring for secondary health concerns like bladder/bowel problems or skin breakdowns. As a person with a spinal cord injury, I have learned over the years how to listen to my body and understand how it works differently than a body that has not sustained a T-12 complete injury. I know what works and does not work for me and I am very good at communicating that to the medical professionals whom I encounter.

The medical needs of a person who has sustained a spinal cord injury can be separated into several components. First is the immediate acute care and rehabilitation, where the individual's condition is stabilized and secondary conditions are treated. Patients also may enter into a six to eight-week intensive inpatient rehabilitation program. During this time the individual is going through major periods of adjustment, looking for answers, both physically and emotionally, and more often than not, ignoring those answers because the person is not ready to face a future as it is now laid out. During this time the individual must learn things all over again, from how to dress to how to empty the bladder. It is the role of the medical practitioners to provide information and guidance in increments that the person can digest. Just as some people recover from open heart surgery faster than others, some individuals accept their injuries faster than others. We all have encountered the "super-stars" of rehabilitation and marvel at their ability to accept their disability and not let it be more than a temporary inconvenience in their quest for independence. However, we cannot become impatient with those who take longer to accept their injury and the resultant changes in their lives.

The loss of control that a person feels over their entire existence is only magnified by the loss of control over their own bodies. As a result, individuals who have sustained spinal cord injuries often rebel against the people whom they most closely identify with their predicament - mainly the medical practitioners. This rebellion may be in the form of noncompliance with instructions, abuse of drugs and/or alcohol or symptoms of depression. It is vital that if and when these issues present themselves they be addressed immediately and

forcefully because if they are allowed to continue it will have a devastating impact on the long-range outcome of the patient's ultimate recovery.

I use the word recovery because I believe that it is the second and longest component of a person's life after a spinal cord injury. While at the present time it is medically impossible to repair the damage to an injured spinal cord, I believe that it is possible to "recover" and live a full and satisfying life very close to the life one may have led prior to the injury. During this "recovery" period access to medical care and preventative treatment is most important for a person with a SCI. As the person begins to learn how his/her body is now functioning and has relearned how to perform the tasks we all need to do to get through the day, he/she will have questions about how one does the things they until recently took for granted. They will have to deal with neurogenic bladders and bowels, they will have to be concerned about skin integrity, they will have questions about sexuality. It is during this time that information and guidance will be the most important items that medical practitioners can offer. It is the prescription of time and concern that is most needed.

As people with an SCI learn about the injury, they will begin to understand how their bodies will tell them there is something wrong. They will be able to tell when they are coming down with a urinary tract infection, for example, before they can even get to a physician for diagnostic testing. They



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will describe certain symptoms which may indicate one diagnosis when it may in fact be something else entirely. The point I am trying to make is this. As individuals become adjusted to their injuries they will begin to understand the changes that have occurred in their bodies and be able to assist greatly in the diagnostic process. It is important to listen to people as they listen to their bodies. It is also sometimes necessary to guide them through this process so that they may become active participants in their own wellness. This process is like a partnership and will go a long way towards guaranteeing good health for those people in the future.

The health care that a person with an SCI requires is not much different in practice from that required by the non-disabled individual. The difference lies in the manner in which it is delivered. A much more personal and holistic method is needed because a person with an SCI may have needs that range from Urology to Orthopedics, from Neurology to Physiatry. A person with an SCI will have more medical needs than a person without a disability. As long as they are met in a comprehensive and personal manner then the ultimate "recovery" of that person will never be in doubt. They will be able to achieve any goal that they set for themselves and will be able to lead lives in a manner which will not only be fulfilling to them but will be of consequence to those

around them. As a person with an SCI, I have learned that it would not have been possible for me to attain what I have to this point without the assistance and guidance of the many medical practitioners whom I have had the pleasure of working with. It is only through this partnership that I will be able to enjoy good health and be able to continue working towards the goals that I have set for myself. I will have a SCI for the rest of my life but I believe that I have "recovered" from my injury and with the continued assistance of medical practitioners of all types will continue to live the life that was intended for me. It is through this partnership that I, and others with an SCI, can access quality health care now and in the future and use this partnership to maintain our health, our life, and our dreams.

The most important thing to consider when a person with a spinal cord injury attempts to access health care is not whether there is an office ramp for the person's wheelchair, but whether there is access to information that will help this person accept and live his/her life with the injury.



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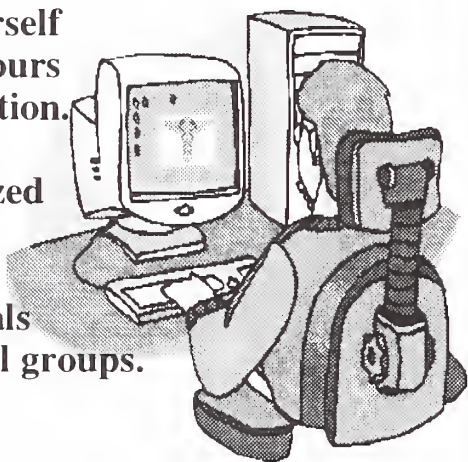
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Overview of Rhode Island Tobacco Laws

Maureen G. Glynn, JD

Rhode Island law recognizes the adverse impact of tobacco usage and the "... escalating financial burden borne by every business, large and small, and every person, smoker and nonsmoker, in Rhode Island."¹ Consequently, the state has enacted laws related to tobacco. For a list of state statutes, please refer to <http://www.ritobaccocontrolnet.com/statlaws.htm>. For a list of Rhode Island municipal ordinances governing tobacco, please refer to <http://www.ritobaccocontrolnet.com/ORDINANCE.HTM>. Some laws pertain to licensing and taxation of the sale of tobacco products. Other laws address tobacco usage, particularly by minors. For purposes of this article, Rhode Island tobacco laws can be categorized into three broad areas: taxation, tobacco control and prevention, and pollution as a result of tobacco products; however, the categories may not be mutually exclusive.

For physicians, the tobacco control and prevention laws are the most salient. A fundamental tenet of Rhode Island tobacco law is that adults have the right to choose whether or not to use tobacco products but such freedom of choice also carries responsibilities. These responsibilities include preventing minors from having access to tobacco products, protecting others from the effect of smoking, and making an informed decision whether or not to smoke.

Rhode Island laws codify some of these responsibilities. Specifically, the sale, gift, delivery, or procurement of tobacco products to or for minors constitutes a violation. Similarly, the law prohibits smoking in certain places - another violation.² An entire regulatory scheme to prevent sales to, delivery of, or gifts of tobacco products to minors has been enacted by the General Assembly, is coordinated by the Rhode Island Department of Health (RIDOH), and prosecuted by the Rhode Island Department of Attorney General.³ The regulatory scheme provides that tobacco vending machines must contain electronic locks, unless they are located within facilities that permit only people age 21 and over.⁴ Frequently, minors cannot afford to purchase a full package of 20 cigarettes. Therefore, it is illegal to sell "loosies" i.e., cigarettes sold in quantities of less than 20 cigarettes to a package.⁵ Purveyors of tobacco products must post notices in red bold letters at least 3/8 inch high on a white background and approved by the RIDOH stating that "THE SALE OF CIGARETTES AND OTHER TOBACCO PRODUCTS TO PERSONS UNDER THE AGE OF 18 IS AGAINST THE RHODE ISLAND LAW ... [and] PHOTO ID FOR PROOF OF AGE IS REQUIRED FOR PURCHASES."⁶ A vestigial 19th century "morality law" still stands, making it a violation for a person under 16 years of age to smoke or chew tobacco, in any form, in any public place.

{An} employer may choose to prohibit smoking in the workplace or accommodate both the smokers and nonsmokers. If the employer permits smoking, then s/he must accommodate both the smokers and the nonsmokers.



Although the penalties for violating Rhode Island tobacco laws are *de minimus* compared to the harm to society, there are, nonetheless, penalties, ranging from fines (which vary according to the type of violation and the number of violations) to revocation of the license to sell tobacco products.⁷ (The 19th century law prohibiting persons under age 16 from using tobacco in a public place specified a penalty of "no more than \$5 for each offense," but in the 19th century \$5 constituted a substantial sum.)⁸ Generally, prosecution of teenage-smoking "violations," including oversight of stores that sell tobacco, falls to municipal police departments, not the state police.

As for environmental pollution, the General Assembly has found that "[s]moking tobacco in any form is a public nuisance and dangerous to public health."⁹ Therefore, the General Assembly outlawed smoking in government buildings, auditoriums, elevators, indoor movie theaters, libraries, art galleries, museums, concert halls, auditoriums, buses, schools (except of science/clinical studies), public hallways in court buildings, hallways of elderly housing complexes, supermarkets, medical offices, public laundries, and hospitals, provided the places are either used by or open to the public.¹⁰ However, even in these locations, smoking may be permitted in areas that are separated from the general public areas and identified by signs as smoking areas.¹¹ Excluding bars, nightclubs, lounges, dance clubs, and privately sponsored social events, public eating facilities which seat 50 or more persons must have separate nonsmoking and smoking areas and notify the patrons of such areas.¹² The RIDOH, in conjunction with the America Cancer Society and the American Lung Association, maintains a list of smokeless restaurants

Office of Health Care Advocate

The General Assembly created the office of Health Care Advocate within the Department of the Attorney General to give Rhode Islanders an advocate to protect access to quality and affordable health care. Rhode Island is the first state in the nation to create this office.

The Health Care Advocate oversees such diverse actions as hospital mergers, the tobacco settlement, health insurance trends, health legislation, and public education.

Maureen Glynn will be keeping readers abreast of the Advocate's actions in future Judicial Diagnosis columns.

in Rhode Island (<http://www.ritobaccocontrolnet.com/SFDINCOU.html>).

Supporting nonsmokers' right to unpolluted air, the General Assembly enacted the Workplace Smoking Pollution Control Act,¹³ which seeks "(1) to protect the public health and welfare by regulating smoking in the workplace and (2) to minimize the toxic effects of smoking in the workplace by requiring an employer to adopt a policy that will accommodate, insofar as possible, the preferences of nonsmokers and smokers."¹⁴ The Act does not create any rights to sue the employer or to limit the employer's decision to prohibit smoking in the workplace. The employer may choose to prohibit smoking in the workplace or accommodate both the smokers and nonsmokers. If the employer permits smoking, then s/he must accommodate both the smokers and the nonsmokers. Employers are not required to construct separate smoking and nonsmoking areas, but may use the existing ventilation system or existing partitions or separations to provide both smoking and nonsmoking areas. Failure to comply with the Workplace Smoking Pollution Control Act can result in prosecution by the Attorney General.¹⁵ Except for nonprofit organizations whose primary purpose is to discourage tobacco usage by the public, employers may not prohibit smoking or tobacco usage outside of the workplace as a condition of employment.¹⁶ Moreover, employers cannot discriminate against an employee concerning compensation or conditions and terms of employment due to an employee's use of tobacco products outside of the workplace.¹⁷

Admittedly, no law can be solely responsible for shaping an individual's behavior; and for a smoker the addictive power of tobacco may override both legislative initiatives and health concerns.

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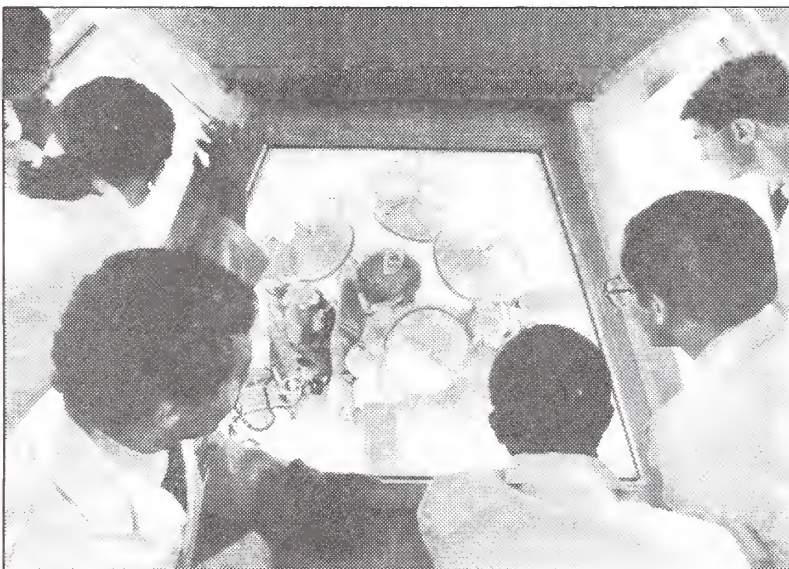
1. R.I. Gen. Law § 11-9-13.3.
2. R.I. Gen. Law § 11-9-13.
3. R.I. Gen. Laws § 11-9-13.6
4. R.I. Gen. Law § 11-9-13.1
5. R.I. Gen. Law § 11-9-13.1(b)
6. R.I. Gen. Law § 11-9-13.7
7. R.I. Gen. Law § 11-9-13.1(d)-(e); 11-9-13.10(a); 11-9-13.11(a); 11-9-13.10(d); and 11-9-13.13
8. R.I. Gen. Law § 11-9-14
9. R.I. Gen. Law § 23-20-6-2
10. R.I. Gen. Law § 23-20-6-2(a)
11. R.I. Gen. Law § 23-20-6-2(d)
12. R.I. Gen. Law § 23-20-6-2(e)(1)
13. R.I. Gen. Laws § 23-20.7-1 through 7
14. R.I. Gen. Law § 23-20.7-3
15. R.I. Gen. Law § 23-20.7-7
16. R.I. Gen. Law § 23-20.7.1-1
17. Except for pregnant women covered by Medical Assistance / RITE Start, Rhode Island does not mandate health insurance companies to provide smoking cessation treatment. Nonetheless, many health insurance policies provide smoking cessation benefits. Also, the Cancer Prevention Research Center at the University of Rhode Island and the Behavioral Medicine Department at Brown University School of Medicine offer smoking cessation programs.

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“TAKE CARE Rhode Island” Coalition

David R. Gifford, MD, MPH, and Kathryn M. Harrison, CPHQ

In 1992, the Health Care Financing Administration (HCFA) initiated the Health Care Quality Improvement Program (HCQIP) coordinated by the Peer Review Organization Program. As part of this effort, Rhode Island Quality Partners, Inc. (RIQP), the Peer Review Organization (PRO) for Rhode Island collaborated with the hospitals and managed care organizations in the state to evaluate and improve care in the hospital setting. Beginning in the fall of 1999, HCFA asked each PRO in the country to expand its efforts to include the entire state population and to focus on eight specific clinical areas: acute myocardial infarction (AMI), congestive heart failure (CHF), stroke, atrial fibrillation, pneumonia, diabetes, mammography utilization and influenza/pneumococcal vaccinations.

At a press conference held at the State House on February 14th, RIQP announced the formation of TAKE CARE Rhode Island, a broad-based coalition of health care providers and organizations in Rhode Island (see Table 2 for current members). TAKE CARE Rhode Island anticipates growing in membership. The idea for the coalition developed as a result of meetings between RIQP, hospitals and managed care plans in Rhode Island to discuss how Rhode Island would respond to HCFA's initiative in these eight areas. The coalition grew to encompass government agencies, physician groups, specialty societies, and patient advocacy organizations and represents a

unique collaboration of the many institutions, groups and organizations that are responsible for ensuring the quality of care provided to Rhode Islanders. This broad-based coalition of health care providers is the first collaboration of its kind in the nation to focus on quality improvement for the entire state.

During initial meetings, members of the group voiced

Table 1. TAKE CARE Rhode Island endorsed hospital-based quality indicators.

Condition	Quality Indicator focus
Acute Myocardial Infarction	Aspirin use Beta-Blocker use Lipid lowering medication use ACE-inhibitor use for systolic dysfunction Thrombolytic use Smoking cessation counseling
Congestive Heart Failure	ACE-inhibitor use Weight monitoring Discharge instructions about disease management
Atrial Fibrillation	Warfarin use Discharge instructions about warfarin
Stroke/Transient Ischemic Attack	Antiplatelet use Elimination of sublingual nifedipine Assessment for thrombolytics Thrombolytic use
Pneumonia	Time to antibiotic administration Appropriate antibiotics initiated* Blood cultures prior to antibiotics Influenza and Pneumococcal vaccination rates

For detailed definitions of any of the quality indicators, including the inclusion and exclusion criteria used to calculate the quality indicator, please contact Kathryn Harrison.

***Appropriate antibiotic initiated per American Thoracic Society and the Infectious Diseases Society of America guidelines**

Non-ICU admissions:

- β -lactam monotherapy IV, or - β -lactam (IV) + macrolide_ (IV or PO), or -Quinolone monotherapy (IV or PO).

ICU admissions:

- β -lactam (IV) + macrolide_(IV) , or - β -lactam (IV) + -quinolone_(IV)

If documented β -lactam allergy:

-Quinolone + Clindamycin (IV) , or -Quinolone + Vancomycin (IV)

Abbreviations Used:

AMI	acute myocardial infarction
CHF	congestive heart failure
HCFA	Health Care Financing Administration
HCQIP	Health Care Quality Improvement Program
PRO	Peer Review Organization
RIQP	Rhode Island Quality Partners

concerns about the number of different data collection requirements, guidelines, and practice tools for the same condition that are in use across the state, many of which varied only slightly. By working together, the TAKE CARE Rhode Island coalition hopes to reduce this variation and facilitate the development of a uniform, systematic approach to measuring quality in the hospital setting. For example, the coalition is currently working to endorse state-wide AMI and CHF guidelines from the American Heart Association/American College of Cardiology; uniform data collection instruments to compare practices between facilities; and standardized patient education materials (e.g. smoking cessation counseling material) so that physicians and other health care providers will no longer face having to select from similar, but different, materials on the same topic.

In keeping with HCFA's national effort, the coalition has endorsed a set of quality indicators for five common conditions: AMI, CHF, atrial fibrillation, stroke, and community acquired pneumonia. These quality indicators focus on treatments and interventions that have been shown to improve patient outcomes and survival. They include: prescribing aspirin, beta-blockers, thrombolytics, and cholesterol lowering agents for patients with AMI; ACE-inhibitors for patients with CHF; anticoagulation therapy for patients with atrial fibrillation; antiplatelet therapy for patients with stroke or transient ischemic attack; and prescribing antibiotics in a timely fashion for hospitalized patients with pneumonia (Table 1). As the coalition gathers momentum, its focus will expand to include outpatient, long-term care, and home care settings.

Preliminary results from data collection efforts conducted among hospitalized patients in the latter half of 1998, from all acute care hospitals in the state, indicate that Rhode Island is doing well compared to rest of the nation in the use of beta

blockers in AMI, use of ACE inhibitors for CHF, appropriate use of antibiotics for patients with pneumonia, and warfarin for patients with atrial fibrillation. However, there is still room for improvement within these areas. For example, it appears that many patients with atrial fibrillation, without contra-indications for warfarin, did not receive warfarin.

For other quality indicators, Rhode Island did not fare as well. Early use of aspirin, smoking cessation counseling, and use of thrombolytics in patients with AMI; initiation of antibiotics under 8 hours for patients with pneumonia; and use of influenza and pneumococcal vaccines were below national averages. For example, in Rhode Island a significant number of patients who smoke and experienced an AMI did not have any documentation in the medical record about smoking cessation counseling at discharge. A physician's recommendation to stop smoking is one of the most effective interventions to change patients' smoking habits. TAKE CARE Rhode Island is working to develop smoking cessation material that can better help Rhode Island reduce smoking rates.

Part of the unique aspect of this coalition is the opportunity for members to share information and experiences about quality improvement efforts that will facilitate more rapid improvement across the state. Any physician, physician group, health care provider, or other group wishing to join this effort or who would like additional information should contact David Gifford, MD, MPH, or Kathryn Harrison, CPHQ, at RIQP.

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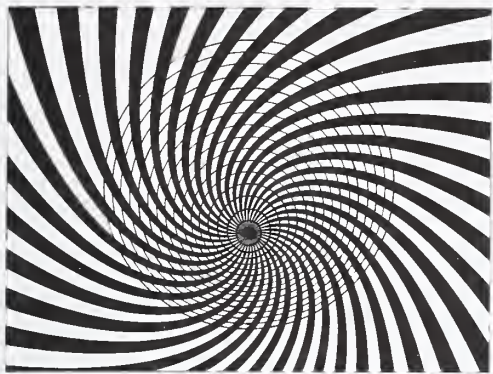
e-mail: ripro.kharriso@sdps.org

**Table 2. Current Members of
TAKE CARE Rhode Island**

American Heart Association, New England Affiliate
Blue Cross Blue Shield of Rhode Island/
Blue CHIP Coordinated Health Partners
Coastal Telesis
Rhode Island Department of Elderly Affairs
Rhode Island Department of Health
Rhode Island Department of Human Services
Kent County Memorial Hospital
Hospital Association of Rhode Island
Landmark Medical Center
Lifespan/Physician Professional Services Organization
Memorial Hospital
Newport Hospital
Rhode Island Hospital
Rhode Island Medical Society
Rhode Island Medicare Carrier and Fiscal Intermediary
Rhode Island Quality Partners
Roger Williams Medical Center
St. Joseph Health Services of Rhode Island
South County Hospital
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The Westerly Hospital
United Healthcare of New England
University Medicine Foundation, Inc.

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The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.



IMAGES IN MEDICINE

Benign Schwannoma

David P. Neumann, MD

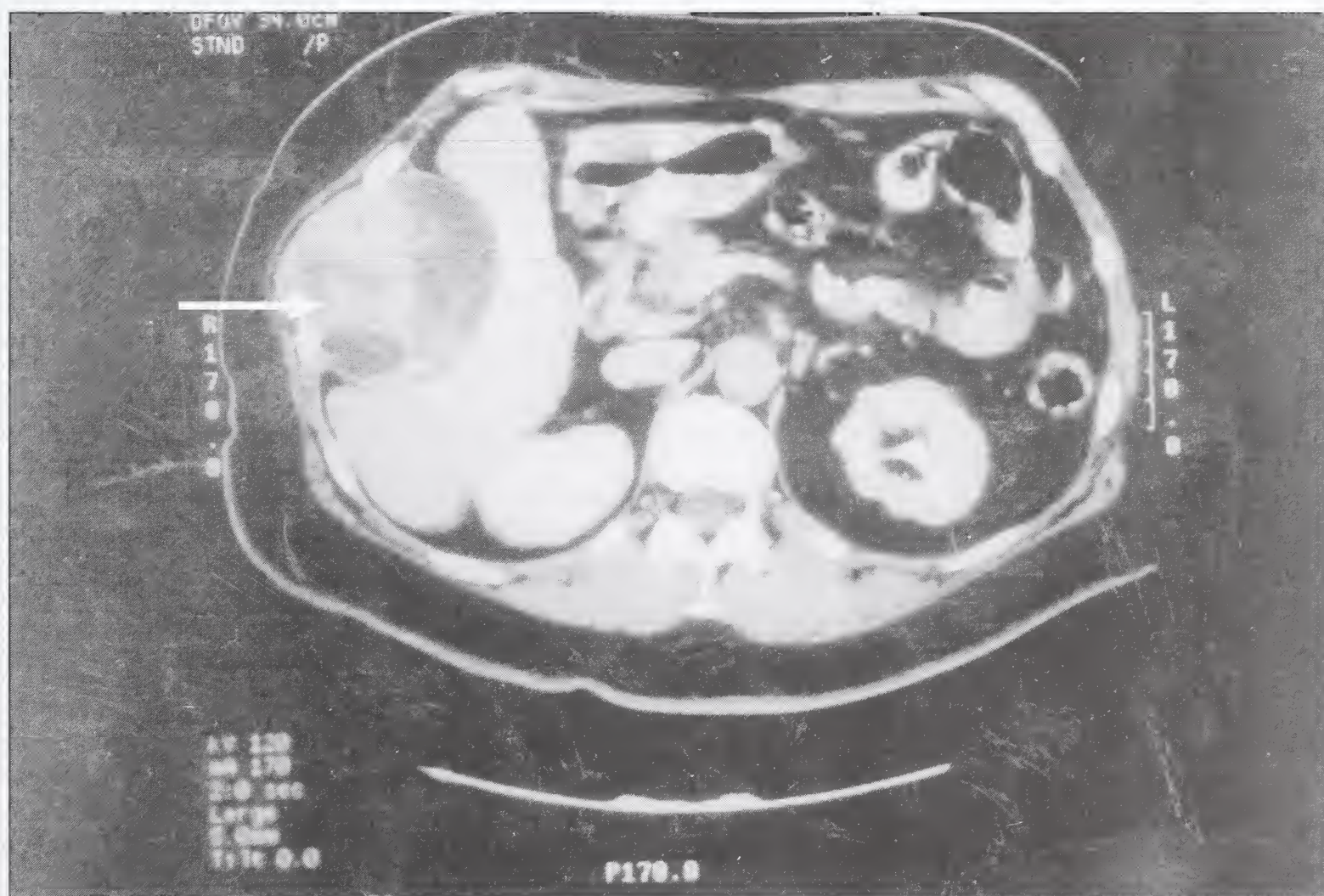
A 63 year old woman presented with chronic right upper quadrant pain and a palpable right lateral thoracoabdominal mass. Her past medical history was unremarkable. CT scan (Figure 1) demonstrated a 10 cm round, well-defined heterogeneous non-calcified soft tissue mass arising from the right lower and lateral chest wall. The lesion expanded the intercostal space without rib destruction and displaced but did not invade the adjacent liver. No adenopathy or distant metastases were seen. The differential diagnosis included malignant fibrous histiocytoma, liposarcoma and fibrosarcoma as well as peripheral nerve tumors and desmoid tumor. At biopsy and subsequent resection, a tumor with predominantly increased cellularity, composed of elongated and wavy cells arranged in palisade and whorl formation, and with few mitotic figures was described. A diagnosis of benign cellular schwannoma (neurilemmoma) was made and confirmed with special immunohistochemistry and electron microscopy studies. These tumors are typically solitary

and discovered in the third decade of life with no sex predilection. The large size of the lesion and the patient's age at diagnosis were unusual. After more than 5 years, the patient had no complaints and no further imaging had been performed.

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Hospitalizations for Spinal Cord Injuries, 1994-1998

Jay S. Buechner, PhD, Mary C. Speare, MA, Janice Fontes, MA

Injuries to the spinal cord are relatively rare, but can be serious and debilitating, as they often result in death or lifelong paraplegia or quadriplegia. Because of their cost to society in terms of medical care and lost productivity, because of the suffering experienced by victims, and because of the emotional toll they inflict on families and friends of victims, spinal cord injuries (SCIs) are high priorities for injury prevention programs.

Nearly every person who suffers a SCI and survives the initial trauma is admitted to an acute care hospital. Thus, hospitalizations for SCI serve as an acceptable proxy for the incidence of non-fatal SCI. The following analysis presents data from Rhode Island hospitals on discharges with SCI and related diagnoses.

charges that may prove to be cases after inspection of the medical record ("possible cases"). (Table 1) Information on the patient's

age, sex, and discharge status and on the cause of injury (e.g., fall, motor vehicle crash) were obtained from the discharge database. Discharges from October 1, 1993, through September 30, 1998, corresponding to hospital fiscal years 1994-1998, were included in the analysis. Age-specific rates were computed using state population estimates for 1994 through 1998 from the federal Bureau of the Census.²

Abbreviations Used:

CDC	Centers for Disease Control and Prevention's
SCI	spinal cord injury
TBI	traumatic brain injury

Methods

Hospitalizations with SCI and related diagnoses were identified from hospital discharge data for Rhode Island acute care hospitals using the Centers for Disease Control and Prevention's (CDC) case definition for spinal cord injuries.¹ For use with hospital discharge data, the CDC case definition has been translated into two lists of disease codes, those identifying discharges that can be presumed to be cases of spinal cord injury ("cases") and those identifying other dis-

Results

During the five-year period studied, there were 277 discharges from Rhode Island hospitals with a principal or additional diagnosis of SCI, an average of 55 per year, and another 2,002 discharges with possible SCI, an average of 400 per year. (Table 1) Of the possible cases, the large majority were fractures of the vertebral column with no mention of accompanying SCI. Other possible cases included discharges for late effects of SCI or fractures of the spine, presumably representing readmissions sometime after the initial treatment at time of injury. Reviews of the medical records of a sample of possible cases have revealed that very few are true SCI cases, so all results hereafter are based only on discharges with a principal or additional diagnosis of SCI.

The rates of hospitalization for SCI, based on the CDC definition for cases, varied by age from 0.9 per 100,000 population among persons ages 0-14 years to 9.9 per 100,000 among persons ages 65 and older, with an intermediate peak among persons ages 15-24 years. (Figure 1) Males comprised two-thirds of SCI cases overall and experienced higher hospitalization rates in each age group. Among persons under age 45, hospitalization rates for males were typically three times the rates for females, and among those ages 65 and older, the rates for males were higher than rates for females by 60% or more.

The largest number of SCIs were caused by falls, followed by motor vehicle crashes. Other causes were relatively minor contribu-

Table 1.
Hospital Discharges with Spinal Cord Injury (SCI) and Possible SCI,
by Diagnosis, Rhode Island, October 1, 1993 - September 30, 1998

Diagnosis	Discharges	
	Number	Percent
SCI Cases	277	12.2
Fracture of vertebral column with spinal cord injury	131	5.7
Spinal cord injury without evidence of spinal bone injury	146	6.4
Possible SCI Cases	2002	87.8
Fracture of vertebral column without mention of spinal cord injury	1652	72.5
Late effect of spinal cord injury	176	7.7
Injury to nerve roots and spinal plexus	32	1.4
Late effect of fracture of spine and trunk without mention of spinal cord lesion	134	5.9
Late effect of injury to nerve root, spinal plexus, and other nerves of trunk	8	0.3
Total	2279	100.0

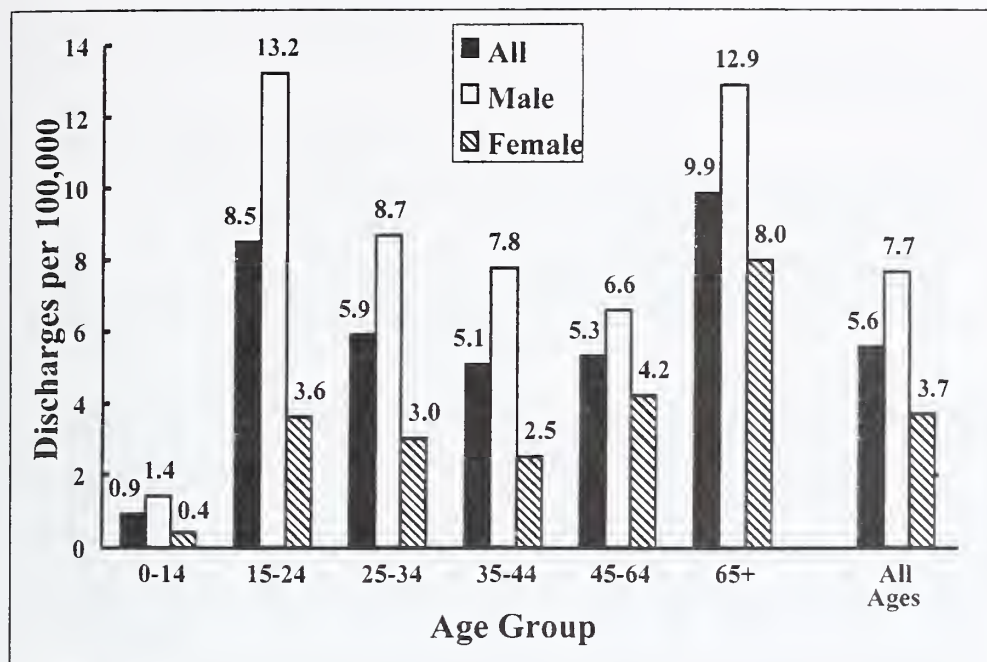


Figure 1. Hospitalizations per 100,000 Population with Any Diagnosis of Spinal Cord Injury, by Age Group and Sex, Rhode Island, Fiscal 1994-1998 (Annual Average).

tors, including assaults (5%) and self-inflicted injuries (1%). (Figure 2) Among the elderly, falls caused over half (58%) of all SCIs and motor vehicle crashes only 14%. Among those ages 15-24, the pattern was reversed, with fewer SCIs caused by falls (28%) than by motor vehicles (38%).

Of those treated for SCIs, only one-third were discharged to home without some provision for ongoing care. (Figure 3) Of those receiving additional care, the largest number were transferred to a non-acute inpatient institution, presumably a rehabilitation facility (30%). Smaller proportions were discharged to home health care (16%), nursing homes (8%), or other acute-care hospitals (3%). Eight percent of SCI admissions died in the hospital.

Discussion

Injuries to the central nervous system, which include spinal cord injuries and the more numerous traumatic brain injuries, have been designated by the National Centers for Injury Prevention and Control, CDC, as a high-priority focus for public health injury programs. In Rhode Island, the General Assembly originally mandated the reporting

of traumatic brain injuries (TBI) to a central registry in 1987. Under the legislation, hospitals were required to report any discharge with a head injury diagnosis to the Office of Vocational Services, Department of Human Services, for the purpose of helping persons with brain injuries gain access to appropriate medical and social services. In 1997 the legislation was amended to transfer responsibility for the registry to the Department of Health and to expand mandated reporting to include spinal cord injuries. In the same year, CDC funded the Department to develop a brain injury surveillance system based on the Traumatic Brain Injury Registry and the statewide hospital discharge data.

In response to the legislative mandate, the Department of Health is preparing regulations that will establish the reporting requirements for spinal cord injuries. In addition, CDC funding is helping develop an associated SCI surveillance system. These information resources will help persons with SCI and will support SCI prevention programs, just as the TBI Registry and surveillance system have served persons with brain injuries and programs addressing TBI prevention.

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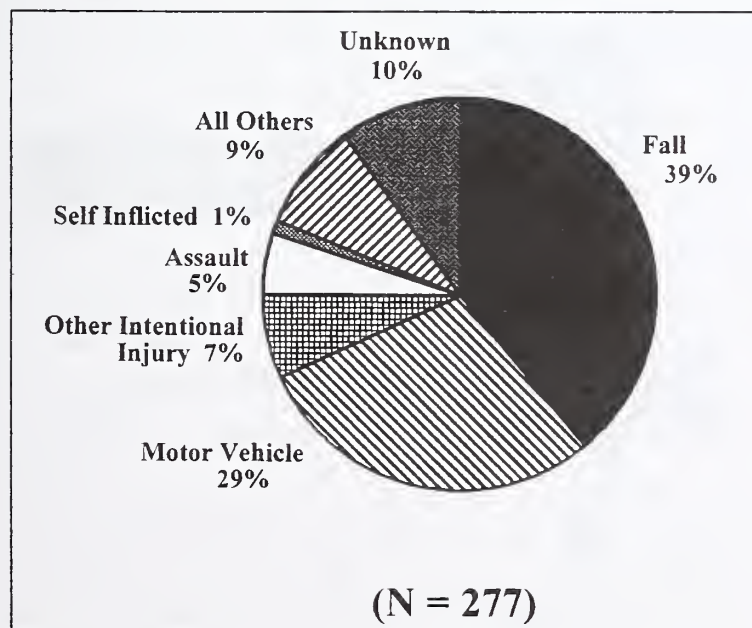


Figure 2. Cause of Injury for Hospitalizations with Any Diagnosis of Spinal Cord Injury, Rhode Island, Fiscal 1994-1998

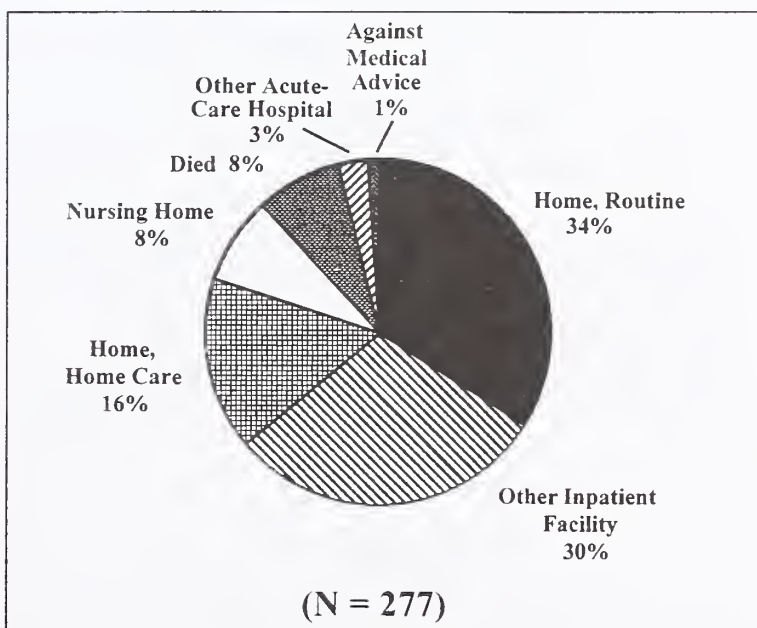


Figure 3. Discharge Disposition for Hospitalizations with Any Diagnosis of Spinal Cord Injury, Rhode Island, Fiscal 1994-1998



Vital Statistics

Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Underlying Cause of Death	Reporting Period			
	Mar. 1999	12 Months Ending with Mar. 1999		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	276	3,047	308.3	3,720.5
Malignant Neoplasms	206	2,511	254.0	6,698.0**
Cerebrovascular Diseases	46	572	57.9	776.0
Injuries (Accident/Suicide/Homicide)	30	361	36.5	7,100.0
COPD	55	466	47.1	420.0

Vital Events	Reporting Period		
	September 1999	12 Months Ending with September 1999	
	Number	Number	Rates
Live Births	1,234	13,496	13.7*
Deaths	730	9,854	10.0*
Infant Deaths	(10)	(93)	6.9#
Neonatal deaths	(9)	(69)	5.1#
Marriages	979	7,693	7.8*
Divorces	172	2,830	2.9*
Induced Terminations	384	4,868	360.7#
Spontaneous Fetal Deaths	89	1,022	75.7#
Under 20 weeks gestation	(80)	(951)	70.5#
20+ weeks gestation	(9)	(71)	5.3#

**Excludes one death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population

Rates per 1,000 live births

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IN MEMORIAM, 1999

(the following names were omitted from the February listing)

Richard P. D'Amico, MD

Rudolph W. Pearson, MD

Nathaniel D. Robinson, MD

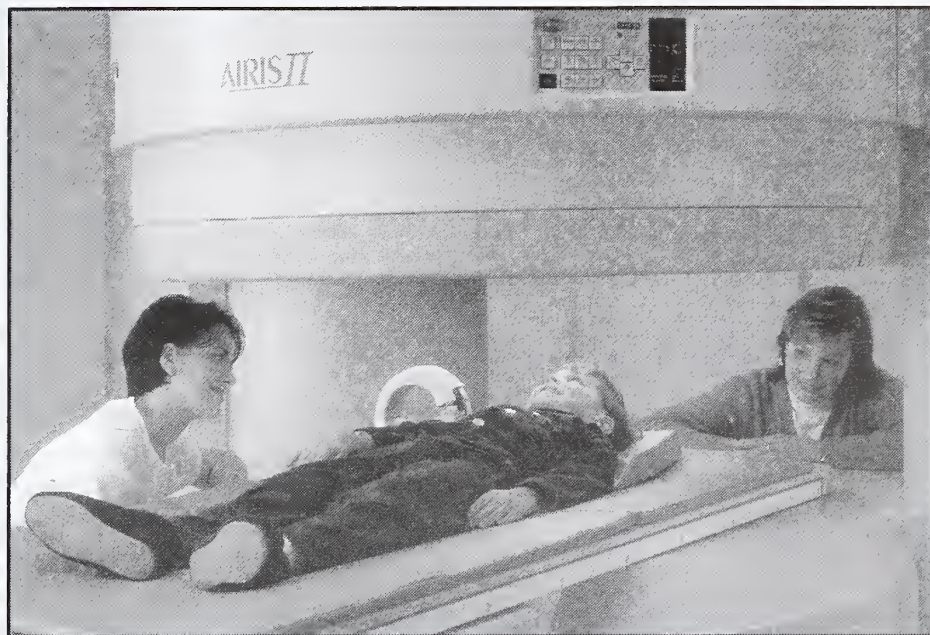


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NINETY YEARS AGO

[MARCH, 1910]

An editorial on "Proposed Tuberculin Legislation" supported the state-mandated testing of cows. The bill, spurred by the discovery that 26 of the 46 cows that supplied milk to the State Sanatorium were infected, "[pitted] public necessity against private advantage," or farmers against everybody else. "The real difficulty will lie in proving to the dairyman that such a law will benefit him inadvertently but surely... He may or may not regard the bounty on condemned cattle as sufficient, but will in any case object to a law which jeopardizes in the future the life of every tuberculous cow. That such a law will safeguard him in the purchase of cattle and abet him in the sale of them...are points which only a considerable foresight, more perhaps than is to be expected on the part of the average farmer, will reveal..."

A second editorial, on "Sterilization of Dejecta," supported the patented invention of Dr. Sheffield Smith of Providence: a device for steam sterilization "that can be applied to the closets of hotels, hospitals and railway coaches..." While hospitals disposed of the soiled clothing and bedding of typhoid patients, "...the danger of transmitting the disease continues long after the 'recovery' of the patient." That recovered patient will travel throughout the country, "distributing infected feces and urine along the railway track and at whatever hotels he may stop."

In "The Use of Bacterial Vaccines in Therapeutic Immunizations," W.G. Dwinell, MD, discussed "what vaccines are, what they do, and how they do it," citing several cases. One patient with recurring attacks of boils (pure staphylococcus) was given an autogenous vaccine, which ended the boils. Another patient, with gonorrhea, was treated with a "personal vaccine," which also worked. Dr. Dwinell, though, cautioned that tuberculosis and septicemic disease might not respond so easily. "We must not by our inoculation accentuate nature's negative phase. And we must constantly bear in mind...the possibility that by importation of a bacterial vaccine into a body of a patient who is already staggering under severe bacterial intoxication, such a further quantum of poison...would just suffice to overtax his power of resistance."

FIFTY YEARS AGO

[MARCH, 1950]

In "The Legal Hazards of the Practice of Medicine," S. Everett Wilkins, Jr., Esq, reminded physicians of their responsibilities to "charity" cases: "...you do not have to accept them, of course, but when you do accept and treat them, you owe them [specified] duties." As for malpractice, Mr. Wilkins noted, "In the final analysis, you will be judged by laymen."

In "The Importance of Diet in the Treatment of Diarrhea in Infancy," Edward Scott O'Keefe, MD, [a Lynn, Massachu-

setts, pediatrician speaking before the Providence Medical Association] argued against the "cure through starvation," proposing instead high-calorie diets for infected infants (33% more calories per kilogram than normal well infants, and 100% to 500% more than many treated infants receive).

In "Lymphoid Polypoid Hyperplasia of the Rectum," Herbert Fanger, MD, and Bernard Virshup, MD, described four cases from Rhode Island Hospital's Institute of Pathology which showed that "a benign condition"... must be carefully differentiated from the malignant lymphoma group."

Henry L.C. Weyler, MD, noted in "Skin Irritation around the Anus due to Aureomycin" that a rash can develop a week to 10 days after starting even low-dose treatment, but since the patient rarely links the rash to the aureomycin, he rarely tells the doctor of the rash.

The Committee on Diabetes reported on Diabetes Detection Week (October 10-16, 1949). The Medical Society joined with Departments of Health, District Nursing Associations, the Department of Education, private laboratories, hospitals, some private schools, radio stations and Ames Company of Elkhart, Indiana (which donated 1000 Clinitest tablets), to encourage all Rhode Islanders to be tested, free, for glycosuria. Of 7320 tests, 319 were positive.

An Editorial on "Rehabilitation" urged clinicians to support post-hospital rehabilitation: "Too frequently, it happens that [a patient] is only partially rehabilitated when he is discharged from the hospital...To stop rehabilitation at this point is to leave the job half done."

TWENTY FIVE YEARS AGO

[MARCH, 1975]

Stanley M. Aronson, MD, in Message from the Dean, reported that 45% of the 58 graduates had matched at one of the four Brown-affiliated hospitals (Rhode Island Hospital, Roger Williams General Hospital, The Miriam Hospital, Memorial Hospital).

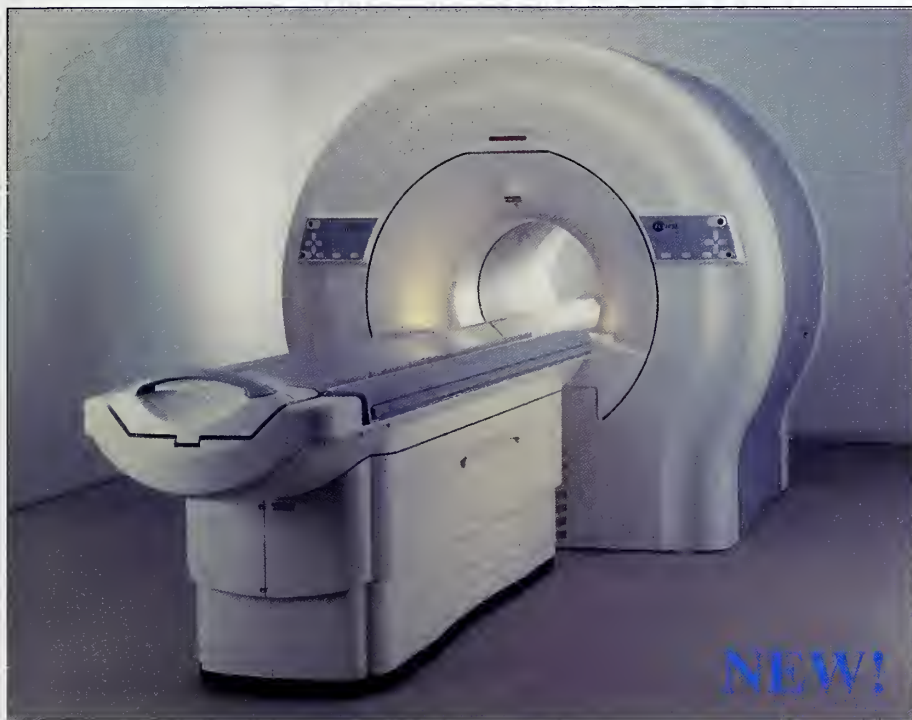
The rest of the issue comprised a festschrift in honor of Fiorindo A. Simeone, retiring from the Department of Surgery at Miriam Hospital. As a Fellow at the Massachusetts General Hospital, Dr. Simeone had worked to create the first physiologically-based and clinically-oriented peripheral vascular laboratory. Among the papers were "Phleborheography: A New Non-Invasive Method of Diagnosing Deep Venous Thrombosis of Lower Extremity," by John J. Cranley, MD, Director, Department of Surgery, Good Samaritan Hospital, Cincinnati; "Radiation Effects of Radiodine on the Thyroid," by Brown M. Dobyns, MD, PhD, Professor of Surgery, Case Western Reserve University; "Clotting Factors in Burn Sepsis," by Richard B. Fratianne, MD, Director of the Burn Unit and Associate Professor of Surgery, Case Western; "Microcirculatory Dynamics and the Control of Hemorrhage," by Robert W. Hopkins, MD, from the Miriam Hospital.

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Medicine  Health

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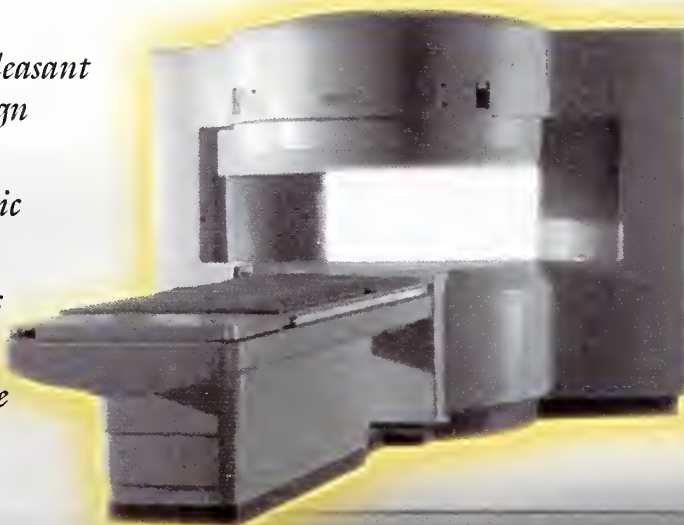


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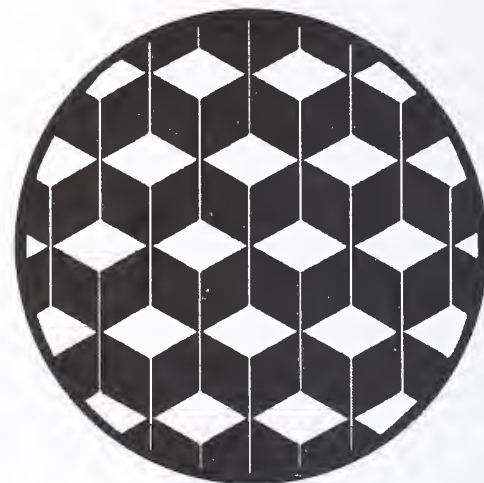
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First Annual April (Fool's) Commentary Cognitive Sinks: The Black Holes of Neuropsychology: A Brief Overview



A REVIEW BACKGROUND

One of the disadvantages of doing classified research is that theories and data can't be published.¹ Since the end of the Cold War, some research areas have lost their national security importance and have therefore been declassified. With the loss of potential strategic importance certain research topics have lost their funding, causing them to remain in a state of suspended animation, awaiting further funding for development.

The work I did on cognitive sinks (CS) is one such research topic and although once considered a high priority area,² with immediate applications for cold and hot war scenarios, it has now fallen completely out of favor and is therefore no longer funded. Publication was forbidden so this report represents the first time these ideas and data have appeared in press. This publication condenses years of hard and often unproductive work and may, hopefully, spur others on to develop insights into this interesting and poorly understood phenomenon. Actual data will be published elsewhere.^{2a}

DEFINITION

A cognitive sink is defined as a person who, without physical contact, lowers the IQ of one or more individuals through social interaction alone. Furthermore, the cognitive sink does not develop an increase in IQ as a result.³

COMMENT

This concept is not strictly defined. Research criteria vary depend-

ing on the study. This research center has used the so called "ten-three" or "ten cubed" definition, defined as a ten-minute exposure producing a ten-point IQ drop lasting at least ten minutes after the exposure ends. The various possible definitions are endless but data clearly indicate that less stringent criteria, for example the "five-three" criteria dramatically increase the prevalence of this property to the point of making it difficult to study, whereas a more restricted definition does not markedly reduce the population with this property. The cognitive sink property is analogous to an astronomical "black hole." Although this is not a medical problem and appears in all settings⁴ it has been studied primarily in the medical setting.

HISTORICAL NOTE

Social psychologists have resisted the concept of cognitive sinks, claiming that violations of the so-called third law of mass psychology, conservation of intelligence, cannot exist.

Example: Subject 3 H 5 (office interaction 5/13/1985)

JF: Tell me about the falls.

CS: Well, I was in the kitchen, and another thing, my legs hurt. Why do my legs hurt?

JF: Are they stiff? Do they. . .

CS: And another thing. I'm constipated. Why don't these suppositories work?

JF: Let's talk about the falling.

CS: That's what I want to know!

JF: What?

CS: The falling. Why am I falling?

JF: How did you fall?

CS: I was in the kitchen because I was hungry. How come I'm always hungry?

I. Do cognitive sinks exist?

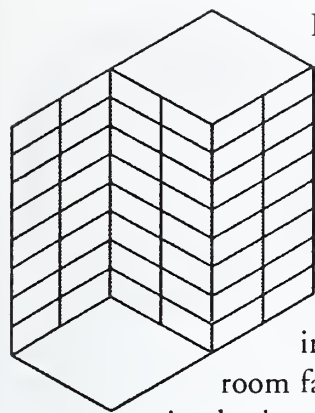
Five studies addressed this issue, three in the United States, one in England and one in Israel. Investigational paradigms were similar. Healthy medical students, ages 21-30, gave written informed consent to participate in a "neuropsychology experiment." All subjects were exposed to individuals with the CS property in double blind, placebo-controlled, crossover trials and all confirmed that such a phenomenon exists.

II. What is the prevalence?

To estimate prevalence one must consider certain properties of the CS. The effect of a single CS varies with the population exposed, so that a CS can be given an "efficiency rating," with 1.0 being the highest. An efficiency rating of 1.0 indicates that 100% of exposed suffer effects whereas a rating of 0.5 implies that 50% of the exposed are affected. For example, a hospital administrator may have a rating of 0.8 on medical personnel and a 0.1 rating on other hospital administrators.⁵

III. How long is the effect?

The duration of an IQ loss varies with the duration of the exposure and the drop in the IQ. Hence, a large drop would predict a long recovery time. It is uncommon, but well described, for an IQ loss to apparently be permanent.



In the famous Tenaflly incident five medical students exposed to a particularly potent CS in a conference room failed to recognize the danger they were in

and remained for two hours before being found by the supervising principal investigator. Three failed out of medical school as a result.

IV. How is the effect transmitted?

Effective communication is required for the effect to occur. While most effects occur via listening, sign language will convey the effects equally well.

Crossed dextral subjects with left hemisphere lesions were less affected than right dominant subjects, suggesting a left hemisphere location for being at risk. If the listener does not understand the CS then the effect is not conveyed. Thus, merely being in the presence of a CS is not sufficient for an IQ loss. Communication over

the telephone may transmit the effect but efficacy drops about 15-20%. Reading is much less effective. Video-tapes are only weakly effective.

V. Is there protection?

A variety of medications have not been protective. A trial of Gingko baloba plus vitamin E is under way. Psychological approaches have not been successful but distractants such as random electrical pain stimulators attached to any body part, large doses of lactulose, cardboard matches used to pry open the eyelids, dextroamphetamine and marijuana all provide significant protection but are not always considered beneficial by the subject. Deep brain stimulation using implanted pacemaker devices appears promising but stimulator parameters and even electrode targets are unclear. One trial, using the pre-chiasmatic nucleus as a target, provided 95% protection but the subjects had to urinate every 15 minutes.

VI. Future directions

The applicability of this research is universal. All of us are under potential attack every day. How to prevent short-term effects and the more nefarious long-term effects has not received

the attention it deserves. We are currently working on rapid screening tests to quickly identify potential CS and study their effects. The public health costs have not been estimated and the ethical issues are immense. What should be done if your teacher, student, mother, brother, child has this property? Will deep brain stimulation be the answer?

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October 26, 1977: A Day to Cherish

Smallpox has been a grim companion of mankind for millennia. Long before the inevitability of death and taxes had been proclaimed, there was the chilling reality that few communities escaped the mortal grasp of smallpox. In England and its Atlantic colonies, where better records had been maintained, about one-tenth of the children, on average, were taken annually by smallpox.

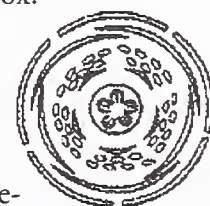
Certainly smallpox was inevitable but people tried to avoid its ravages through prayer, fasting and talismans. In India, for example, statues of the goddess Shatala, consort to Shiva the Destroyer, were erected in countless villages; and whenever smallpox loomed, these shrines were bedecked with flowers and tokens beseeching protection. In medieval France, statues of Saint Nicaise served a similar purpose. The Yoruba of west Africa identified Shopona as the god whose wrath created smallpox.

Smallpox, clearly, was contagious and a frequent fellow traveler of commercial ventures, invading armies, fleeing refugees and religious pilgrimages. The realities of contagion allowed mankind to establish its first meaningful barrier to smallpox. True, many clergy pronounced

smallpox to be a divinely ordained punishment; but Leviticus had specifically instructed the wandering Israelites to segregate those with grievous sores by removing them from the encampment. Quarantine, an obvious response to infectious disease, became an effective means of affording temporary protection against smallpox. Sometimes it was the afflicted who were ostracized; and sometimes it was the entire community which isolated itself from the contaminated world about them.

Somewhere in the distant past, some wise person recognized that when smallpox was inadvertently contracted by skin contamination, the resulting infection tended to be more brief and less lethal. And thus, in many Asian and African communities, was born the concept of intentionally infecting susceptible children as a means of conferring upon them a lifelong immunity to smallpox.

The process, called inoculation, was brought to the attention of England's physicians in 1716. And when Boston was threatened with smallpox in 1721, there were those who urged inoculation as a pre-



ventive intervention. Despite much heated debate, inoculation [later called variolation] was shown to save lives. Inoculation, however, was sparingly employed except by the upper classes; and its suppressive effect on smallpox mortality, therefore, had been minimal. An occasional military leader with vision appreciated the immense advantage of an army invulnerable to smallpox. Washington, for example, had many of his core battalions inoculated.

In the year 1798 a Gloucestershire physician, Edward Jenner, noted that the relatively benign pox-infection of horses and cows was capable of inducing, through contact, a mild, self-limited infection in humans. And further, he observed, persons who had endured this cowpox infection were enduringly protected from smallpox. Jenner then intentionally infected susceptibles with cowpox material thus initiating the process now called vaccination.

When entire communities underwent vaccination, smallpox was suppressed. But most children, particularly from impoverished inner city families, were not vaccinated and smallpox, therefore, continued to flourish through the 19th and early 20th Century. Creighton, the historian, observed that smallpox, in England, "first left the richer classes, then it left the villages, then the provincial towns, to centre itself in the capital."

The first nation to declare itself smallpox-free was Sweden in 1895. Its public health authorities recognized, though, that no nation could feel itself safely removed from the threat of smallpox as long as the disease prevailed else-

where in the world.

In 1966, after years of debate, the World Health Organization [WHO] made the fateful decision to fund a campaign to eradicate smallpox in all nations.

The last cases of smallpox in the Western Hemisphere occurred in Bolivia and in southern Texas. By the end of 1969 North and South America were declared to be free of smallpox. But given the immense traffic in humankind between all continents, it would have been naive to think that this freedom from smallpox could be maintained. All of Europe was free of smallpox by 1972, but in February of that year a Moslem cleric, native to Kosovo, contracted smallpox while on a holy pilgrimage to Mecca. Upon his return to the Balkans, he unknowingly infected some 150 people in his congregation. The Yugoslavian government, led by Marshall Tito, undertook draconian measures to halt the further spread of smallpox. To curtail the movement of people, all forms of national transportation were halted, even those of a humanitarian nature, and the army vaccinated an estimated 18 million people in ten days. The epidemic was aborted, sometimes at the cost of suspending civil liberties.

The global WHO campaign to eradicate smallpox was led by a resourceful American physician named D.A.Henderson. He devised a strategy of enforced vaccination of all humans within a certain radius of each recent smallpox case, thus encircling and confining each potential source of smallpox dissemination. His small army of field workers was trained not only in the recognition of the disease and in technics of mass vaccination but also in such mundane skills as truck engine maintenance. These WHO teams ventured to the most remote, inaccessible corners of the globe. To insure that no case was overlooked, they offered immense monetary rewards to those disclosing patients with smallpox.

By 1974, only Pakistan, Bangladesh, India, Ethiopia and Somalia still harbored cases of active smallpox. By 1977, the disease was confined to the rugged terrain of eastern Ethiopia and the neighboring Ogadan desert lands of Somalia. And on October 26, 1977, the last case of natural smallpox was found and quickly isolated. He was a 27 year old named Ali Maow Maalin. For months thereafter Henderson's teams searched the world but no further cases were discovered. And for the first time in history, an infectious disease had been eradicated from the globe.

Smallpox virus persists today solely in culture tubes within guarded vaults in Atlanta, Georgia, and Novosibirsk, Russia. Routine vaccination has ceased since 1972 leaving the majority of the world's population vulnerable - should the smallpox virus ever be deliberately spread by those intent on bioterrorism.



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— Stanley M. Aronson, MD

A Surgical Approach to Low Back Pain

Beverly C. Walters, MD, MSc, FRSC, FACS, and Gerhard M. Friehs, MD

Although every physician attempts to treat patients presenting with either chronic or acute back pain with non-surgical measures, some patients will fail these treatments and will be sent for consultation with a spine surgeon. The spine surgeon then confers with the non-surgical physician regarding the necessity and potential benefits of surgery, and, in partnership with the patient, a decision is made. Not all patients referred for surgical consult end up having surgery.

Herniated Lumbar Disc

Most patients who present with back pain secondary to lumbar disc herniation will have a unilateral radiculopathy or sciatica as part of the presenting complaint. This is because the annulus fibrosis of the disc is reinforced in the midline by the posterior longitudinal ligament (PLL), causing the disc to rupture out one side or another where there is a deficiency of the PLL. This, in turn, impinges upon the exiting nerve root and causes nerve root irritation with pain and, sometimes, neurological deficit. These patients will often respond well to the non-operative measures, with a resolution of the radicular component.

Some patients do not present with a radiculopathy, but rather with debilitating low back pain which radiates only locally or not at all. These patients require investigation with magnetic resonance imaging (MRI) to ascertain the presence of a surgical lesion when conservative measures fail to reduce symptoms to a tolerable level. Such investigation may reveal a large disc herniation or a small disc herniation in a patient with congenital lumbar spinal stenosis.

LUMBAR SPINAL STENOSIS

Patients with degenerative disease of the lumbar spine typically present with a symptom complex known as

neurogenic claudication. These symptoms consist of pain in the buttocks and posterior thighs upon ambulating or standing for any period of time. The symptoms disappear with recumbency, leaning forward (such as against a shopping cart), or sitting down. Occasionally, however, patients will present with back pain alone, and a plain radiograph will demonstrate degenerative disease. Efforts will not be made to investigate further, since the classic presentation is missing and the patient will be told that s/he will simply have to live with the pain. However, an MRI may well demonstrate severe spinal stenosis with the expected arthropathy and the patient may benefit from surgical intervention.

A probing history must also be taken because these patients will sometimes consider the buttock pain of neurogenic claudication to be the same as back pain, and a remediable lesion may go untreated.

POST-LAMINECTOMY BACK PAIN

After surgery for low back pain, patients may continue to complain of symptoms. It is important to inform patients who present with typical neurogenic claudication that laminectomy is more effective for their buttock and leg pain than their back pain. In this way expectations will not be inappropriate for the outcome of the surgical procedure. However, the patient should improve following laminectomy. If this is not the case, repeat MRI should be carried out to determine whether there is any residual mechanical cause for the persistent pain. This would include residual stenosis, development of mechanical instability with a spondylolisthesis, and arachnoiditis.

With residual stenosis, it is important to understand that re-operation is usually the only option. At surgery, the spinal surgeon uses a combination of observation, radiography, and pal-

Abbreviations Used:

DREZ	dorsal root entry zone
MRI	magnetic resonance imaging
PLL	posterior longitudinal ligament
SCS	spinal cord stimulation

pation to determine whether the decompressive surgery is complete. With experience, the chance of performing incomplete surgery is reduced, but even in the best hands, incomplete surgery sometimes occurs. Although re-operation is somewhat more difficult than original surgery (and the patient should be informed of this), repeat (and more extensive) laminectomy may be the best option. Most patients will understand the need for further surgery and readily agree that it is necessary, particularly if the previous surgical experience has been characterized by early ambulation and early discharge home.

The patient who develops post-laminectomy mechanical instability is typically a young man with a physically demanding occupation such as construction worker or other heavy laborer, or who is obese. This patient typically has a good outcome following spinal stenosis surgery initially and returns to work. He then presents with worsening back pain with no radiation to buttocks or legs. A repeat MRI shows a spondylolisthesis and the patient then must undergo spinal fusion for remediation of symptoms. The risk of this complication of laminectomy decreases with advancing age due to the ankylosis typically found in the elderly in the anterior portion of the spinal column. However, it is important to inform patients pre-operatively that these outcomes do occur.

SPINAL CORD STIMULATION THERAPY

The concept of spinal cord stimulation (SCS) therapy for the suppression of pain is based on the gate control theory developed in 1965.¹ Low-

threshold, large diameter nerve fiber collaterals in the spinal cord are believed to inhibit transmission of pain signals to the brain. The sensation of electrical stimulation of the dorsal spinal cord is usually perceived as paresthesia in the respective dermatomal distributions. In other words, the constant, nagging pain is traded for a warm, tingling sensation in the affected area. The epidural electrode arrays implanted today most likely provide electrical stimulation to the posterior columns, the dorsal horn, dorsal root entry zone (DREZ) and dorsal roots.² Therefore, the previously used term "dorsal column stimulation" may be somewhat misleading.

Indications

Typical indications for SCS are listed in Figure 1. Concerning low back pain, patients become eligible for SCS therapy when there is no identifiable structural lesion on diagnostic studies. In other words, patients who do not have spinal instability, disc herniations, spinal, neuroforaminal or lateral recess stenosis that would require surgical repair, fusion or decompression are generally considered candidates for SCS. These are also patients whose pain has been refractory to the non-surgical methods discussed previously as well as epidural steroids or nerve blocks, behavioral or psychological approaches to pain treatment. It is advisable, and in some states even required by some health insurance carriers, to include a psychologist or psychiatrist into the decision making process for SCS therapy,

especially to identify potential depression or other mood disorders, although there is still debate in the literature whether certain psychological profiles can be used as predictors of good outcome for SCS treatment.^{3,4}

Generally, patients with leg pain respond better to spinal cord stimulation therapy than patients with back pain.⁵ However, new designs of hardware with up to 16 electrodes per array and the use of multiple implanted arrays parallel to each other has shown promising results for excellent stimulation and pain relief in the lower back

*About 75% of patients
find significant persistent
pain relief with
intrathecal continuous
opioid therapy.*



and both legs.

Complications

The possible complications associated with SCS include general surgical complications and the specific risk of spinal cord or nerve damage. The infection rate is comparable to the expected rate after implantation of devices in other regions of the body. Specifically, electrode migration or dislodgment which would result in ineffective stimulation patterns is also possible and best avoided if the patient is instructed to abstain from twisting or bending until the scarring process

is completed approximately 6 weeks after implantation. Spinal cord stimulation is generally considered a low risk procedure.

Outcomes and economic considerations

A good response to spinal cord stimulation therapy is achieved when patients report pain relief of at least 50%. Prospective studies show that this pain relief is achieved in 50-70% of patients in the first two years after implantation.^{6,7} Five years after implantation the positive response rate drops slightly to below 50%.⁷ Compared to alternative therapies, spinal cord stimulation was found to be cost-effective. This is especially true when compared to expensive surgical alternatives or drug therapies with lower efficacy.

INTRATHECAL MORPHINE THERAPY

Treatment with opioids is commonly part of the therapy regimen for patients with intractable pain syndromes. This is also true for patients with intractable back and leg pain. Morphine or morphine-like medications are available as oral, intramuscular, intravenous, subcutaneous, sublingual, nasal, and intrathecal preparations. The intrathecal route of administration allows for application of the medication directly to the site of action in the spinal cord and brain without having to cross the blood brain barrier. This results in a dramatic increase of effectiveness, decrease of required dose (0.3 -1% of the oral or intravenous route) and decrease in side effects such as lethargy, somnolence, or constipation.

When considering intrathecal opioid therapy it is especially important to emphasize the difference between drug tolerance, physical drug dependence, and drug addiction.⁸ Unfortunately, misinterpretation of these terms has often led to undertreatment of pain. With intrathecal opioid therapy becoming widely available and accepted, the often irrational fear of opioids and false belief that morphine always causes addiction will hopefully soon be eradicated.

Figure 1. Common indications for spinal cord stimulation therapy (in alphabetical order)

arachnoiditis
cardiac angina pain
"failed back syndrome", post laminectomy syndrome
neuralgia syndromes
peripheral neuropathy
peripheral vascular disease
phantom limb sensation (pain)
radiculopathy
reflex sympathetic dystrophy, causalgia, regional pain syndrome
spinal cord injury

Indications

Patients who are considered appropriate for SCS are generally good candidates for intrathecal morphine therapy. However, because of the potential lifetime commitment to a medication pump, intrathecal morphine therapy is usually reserved for patients who have insufficient pain relief with SCS therapy or are considered poor candidates for it. The importance of patient selection applies to intrathecal drug therapy even more than for other therapies. Contraindications to intrathecal morphine therapy include active untreated depression and other psychopathologies.⁹ Again, the importance of a multidisciplinary approach to pain treatment cannot be overemphasized.

Complications

Possible side effects from intrathecal test injections include post spinal tap headaches and potential injury to nerve roots (especially in patients with arachnoiditis). Side effects from intrathecal morphine include changes in mental status, respiratory depression, pruritus, gastrointestinal side effects such as constipation, cardiovascular side effects like hypotension, and rarely observed phenomena. In our own experience, more than 90 % of well selected patients will experience pain relief from the test injections.

The surgical pump implantation procedure carries general surgical risks (infection, hemorrhage) as well as the risk of complications with the catheter (kinking, holes in the catheter, catheter breaks) or pump itself (mechanical or electrical failure).

Outcomes and economic considerations

About 75% of patients find significant persistent pain relief with intrathecal continuous opioid therapy. Short-term and long-term pain relief after implantation of intrathecal opioid pumps is reported to be 50-70%.^{10,11} Although there is development of tolerance to opioids in 35% of patients with intrathecal therapy, it is much slower than with other delivery forms.

In one study the average intrathecal morphine requirement found to be less than 5 mg / 24 h after more than 3 years of intrathecal therapy.¹²

The cost-effectiveness of long-term intrathecal therapy for pain treatment has been documented extensively. It is estimated that intrathecal opioid therapy is less expensive than comparable alternative treatment if the duration of therapy exceeds 22 months.¹³

Conclusion

While the majority of LBP patients do not require surgery, it is important to recognize those who do and apply the appropriate procedure. Non-surgical treatment is almost always attempted first, and in most cases allows surgery to be avoided. In those in whom an adequate trial of non-surgical methods fails, surgery is considered and the best approach is determined. Outlined here is the application of a systematic assessment of the patient's specific needs in determining the approach that is best in each case.

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A Non-Surgical Approach to Low Back Pain

Donald R. Murphy, DC, DACAN

Low back pain (LBP) has become one of the most common, and most difficult, medical problems, costing \$24 billion (1990) for treatment. With the consideration of costs of disability, lost workforce productivity and other related factors, the cost to society rises to over \$50 billion. In spite of this, disability due to LBP has continued to rise. It is commonly thought that 90% of the people who develop acute LBP recover within 3 months in spite of the type of treatment, or lack of treatment, they receive. However, as Waddell has pointed out,¹ this statistic can lead to a false sense of security because it indicates the percentage that return to work: 15-20% of these patients continue with some degree of symptoms for at least 1 year, and 70% will have 3 or more recurrences over the following several years.¹

Those patients whose acute LBP episode progresses to become a continuous, longstanding problem incur the vast majority of the cost of LBP.²

Widespread chronic disability due to work related back pain is a relatively new phenomenon. As the United States and the rest of the Western world have become more industrialized, the rate of back injury has increased. Yet actual disability due to back pain, i.e., the inability of the patient to engage in normal work and lifestyle activities, has increased primarily since World War II.^{3,4}

It has been said that the passive approach to acute LBP has played a role in the current problem of LBP disability. Waddell³ has stated, "Prolonged bed rest may be the most harmful treatment ever devised, and (is) a potent cause of iatrogenic disability." Yet, in spite of its dem-

Abbreviations Used:

AIB	abnormal illness behavior
CNS	central nervous system
LBP	low back pain

onstrated inappropriateness,⁴ bed rest beyond 2 days is still commonly prescribed in acute LBP. Even the American Medical Association's *Pocket Guide to Back Pain*⁵ recommends bed rest "for a few days or a few weeks."

LOW BACK PAIN IS A SYMPTOM, NOT A DIAGNOSIS

Essential to effective diagnosis and management of LBP is the understanding that LBP is the patient's experience of a series of events. Two patients with pain in the same location and character, and with similar onsets, can have completely different underlying causes of the pain. Therefore, accurate diagnosis is of the utmost importance in formulating an effective management strategy. Unfortunately, this is not easy, because, particularly in the chronic patient, multiple factors, both somatic and psychosocial, often contribute to the clinical picture.

The importance of diagnosis is often overlooked in LBP treatment, and this leads to poor outcomes. In a recent randomized controlled trial by Cherkin, et al⁶ patients were randomized into groups receiving chiropractic manipulation, McKenzie exercise or an educational booklet about LBP. The groups were randomized without regard for diagnosis, and thus without determination as to whether the experimental treatment was appropriate for each patient's specific problem. Each group fared almost equally poorly.

MECHANISMS

Much of the literature presents a bleak picture with regard to the ability to specifically identify those tissues that are responsible for producing pain in patients with LBP.⁷ Nachemson, in an oft-quoted 1983 paper,⁷ stated that a

Figure 1.
Red Flags for Potentially Serious Conditions
(adapted from ref. 14)

1. On History:

Finding	Suggestive of
Major trauma such as auto accident or fall from a height	Fracture
Minor trauma or strenuous lifting in an older or potentially osteoporotic patient	Fracture
Age over 50 or under 20	Tumor or infection
History of cancer	Metastatic disease
Constitutional symptoms such as recent fever, chills or unexplained weight loss	Infection or tumor
Recent bacterial infection, IV drug use, or immune suppression, such as from steroids, transplant or HIV	Infection
Pain that has no mechanical exacerbating or remitting factors	Infection or tumor
Saddle anesthesia	Cauda equina syndrome
Sudden onset of bowel and/or bladder dysfunction	Cauda equina syndrome
Bilateral progressive neurological deficit covering several dermatomes	Cauda equina syndrome

2. On examination

Pinpoint tenderness of the spinous process	Fracture or infection
Fever	Infection
Multisegmental neurologic deficit	Cauda equina syndrome
Hyperreflexia with upgoing toes	Myelopathy

definitive diagnosis can be made in only 20% of patients with LBP. However, many clinicians would disagree, particularly those who use manual procedures. And more recent research suggests that in many patients with LBP, evaluation procedures can allow for identification of key components involved in the development and perpetuation of the pain.⁸

In the acute LBP patient, the first objective for the initial history and examination is the detection of “red flags”⁹ for more potentially serious problems that may require immediate specialist consultation. (Figure 1) The presence of one or more of these red flags may be reason to order imaging, lab work and/or referral.

Another objective of the initial assessment is the identification of the specific tissue that is the primary pain generator. Recent research by Bogduk⁸ demonstrated that, contrary to popular belief, pain generators in many LBP patients can be identified. The tissues that most commonly serve as the primary pain generator appear to be the intervertebral disc and the facet joints, the prevalence of each of which has been shown to be 40%. The prevalence of pain arising from the sacroiliac joint has been shown to be 13%. While this group used invasive and expensive injection techniques, there is some evidence that manual palpation may be effective at identifying pain arising from the facet joints¹⁰ and sacroiliac joints.¹¹ The McKenzie system of response to loading has been shown to be effective in identifying discal pain.¹² If uncertainty exists in spite of these measures, the clinician can use more invasive procedures such as facet injection or discography.

The prevalence of pain arising from muscle in LBP is more controversial, although it is widely believed that myofascial trigger points are a common source of pain.¹³ Pain referral diagrams, knowledge of the typical referral patterns that arise from specific muscles, and careful palpation of these muscles help the clinician to identify those muscles that may be involved.¹³ Radiculopathy is an uncommon⁹ but important cause of pain in LBP syndromes that involve leg pain. It is most often caused by herniated nucleus pulposus and can be detected via

historical factors such as onset of pain after flexion/rotation strain in a young person and through examination by looking for nerve root tension signs and neurologic deficit. Only if uncertainty exists after history and examination is MRI typically necessary, unless surgery is being considered. Figure 2 outlines the important pain generators in LBP and their detection.

Next, the clinician will attempt to identify key contributing factors to the generation of pain. These factors relate to specific areas of dysfunction that may be causing irritation to the tissues that are generating pain, or that may cause pain via hypersensitization of nociceptive pathways in the central nervous system (CNS). One factor is joint dysfunction, defined as “loss of joint-play movement that cannot be produced by voluntary muscles.”¹⁴ Joint dysfunction can cause pain to arise from the joint itself¹⁵ as well as cause “chain reactions”¹⁶ of dysfunction that can affect joints and/or muscles in areas distal from the initial joint. These secondary areas of dysfunction can then become pain generators themselves as well as contribute to the sensitization of the CNS. In addition to joint dysfunction, examination for the presence of muscle dysfunction is performed.¹⁷ This can be identified through history, inspection, palpation and length tests. Faulty movement patterns¹⁸ are contraction of muscles that are carried out in an incoordinated, inefficient manner and are thought to create inordinate stress on the locomotor system as a whole. These can be detected through careful analysis of the patient as s/he performs

certain stereotyped movements such as hip extension, hip abduction and trunk flexion.

Finally, spinal instability can be an important factor in the development of chronic LBP. The concept of spinal instability has changed in recent years. It was previously thought to relate to ligamentous laxity that produced hypermobility and lack of proper maintenance of stability at end ranges. However, research¹⁹ has revealed that intersegmental stability is more closely related to muscular factors than ligamentous. This work has shown that the contraction time of the intersegmental muscles, especially the multifidi, is critical in maintaining stability in the presence of common, everyday perturbations. This stabilizing ability can be measured clinically with relatively simple clinical examination procedures.²⁰

In the subacute or chronic LBP patient, it is also important during the initial evaluation to assess for signs of abnormal illness behavior (AIB) and other psychosocial factors that may be contributing to the disability associated with the pain. These factors may also lead to treatment resistance and may indicate the need for a treatment strategy that addresses the nonorganic along with the organic aspect of the disability. AIB is an inappropriate response to a physical problem in which the patient’s behavior is out of proportion to his/her actual tissue injury.²¹ The patient who exhibits AIB can be detected by the clinician via questionnaire (Illness Behavior Questionnaire or clinical examination (Waddell’s nonorganic signs).

Figure 2	
Most Common Pain Generators in LBP	
<u>Pain Generator</u>	<u>Detection</u>
Facet joint dysfunction	Motion palpation Tissue texture changes Tenderness
Internal disc disruption	Provocation discography Vibration Response to loading (McKenzie)
Myofascial trigger points	Pain diagram Palpation
Radiculopathy	Nerve root tension signs Neurologic deficit

OUTCOME MEASUREMENT

Assessment of outcomes is essential. There are several reliable and valid methods by which the patient can be tracked for clinical progress. Some of these are physical measures; others are questionnaires.

The Oswestry Low Back Pain and Disability Index²² and the Roland-Morris form²³ are questionnaires that address the pain experience itself or the impact that the pain has on everyday activities. Pain intensity is assessed using a Numerical Rating Scale,²³ an instrument comparable to the Visual Analogue Scale,²⁴ but easier to use.

Assessment of the patient's risk of progression to chronic stages is also important. The literature reveals that most of the primary risk factors for chronicity in LBP patients are psychosocial in nature, though some physical measures have been shown to be significant.²⁵ Fear that further movement will damage tissues, discouragement over the disability related to the pain, abnormal illness behavior, negative expectations regarding recovery and job dissatisfaction are examples of psychosocial risk factors for chronicity. Some physical measures have been shown to be helpful as well, including lumbar extensor and abdominal muscle endurance. Figure 2 shows some of the more important risk factors for chronicity that have been demonstrated in the literature.

When the patient at risk is identified, a more rapid progression to more active, aggressive forms of care is applied, to minimize or avoid this potential chronicity. Those patients who are not at risk are treated less aggressively.

NON-SURGICAL TREATMENT

The approach to non-surgical treatment is directed toward dysfunction, rather than pathology. The treatment strategy is designed to address the clinically significant physical and psychosocial dysfunctions that were detected on history and examination. As pointed out in *Acute Low Back Problems in Adults. Clinical Practice Guidelines*, from the Agency for Health Care Policy and Research,⁹ the two treatment approaches with the greatest scientific evidence in support of their efficacy in acute LBP

Two patients with pain in the same location and character, and with similar onsets, can have completely different underlying causes of the pain.

In chronic patients, manipulation and exercise are among the few approaches that have evidence of effectiveness.



are spinal manipulation,^{9,26} directed at the correction of joint dysfunction, and non-steroidal anti-inflammatory drugs or analgesics such as acetaminophen.^{9,27} These are employed in conjunction with the recommendation of and encouragement for early return to activity.⁹ In the majority of acute LBP patients, quick resolution of the problem is seen without residual problems, unless the patient has significant risk factors for becoming chronic.

In chronic patients, manipulation^{28,29} and exercise^{30,31} are among the few approaches that have evidence of effectiveness. While previously it was felt by some that manipulation was only appropriate in the acute stages of LBP, in a recent review of the literature³² Koes, et al stated, "These findings even suggest

that there is more evidence in favor of manipulation for more chronic conditions than for acute conditions." Indeed, a trial by Meade, et al,²⁸ demonstrated that patients with LBP treated by chiropractors showed improved outcomes compared to patients treated in an hospital outpatient facility and that the disparity in outcomes favoring the chiropractic group was most marked in those patients whose pain was most longstanding and whose disability was most severe. A five-year follow up showed continued disparity between the groups, favoring the chiropractic group.³³

Various exercise approaches have demonstrated that "low-tech" spinal stabilization training designed to restore normal mechanisms of maintaining stability of the spine is more effective and less costly than "high-tech" isokinetic strength training³¹ and standard health club-type exercise.³⁴ This spinal stabilization technique is a major aspect of the approach presented here and involves the use of physiologically complex movement patterns that use a minimum of equipment and are easily transferred to home-based care.

It is essential in the chronic patient to address fear avoidance behavior and to teach pain coping strategies.³⁵ In patients whose disability is such that they fail these approaches, multidisciplinary functional restoration, involving physical training along with intensive psychosocial and vocational intervention, is the only approach that has been shown to have significant success.³⁶

Figure 3
Risk Factors for Chronicity

Physical/ Clinical

Hamstring tightness
Flexion ROM
< 1 year since last occurrence
High Oswestry score
History of leg pain
Prolonged sitting posture
Previous history of LBP

Psychosocial

Increased age
Low wages
Divorced/widowed, no children
Less seniority
High Waddell Score
Less educated
Perception of fault
Duration of disability
Workers Comp claim
Fear-avoidance behavior
Focusing on pain
Job dissatisfaction
Poor coping strategies
Social status
Unemployed
Female gender

Surgical treatment is reserved for those patients who demonstrate progressive neurologic deficit and/or intractable leg pain, who fail 4-8 weeks of conservative measures, and in whom a demonstrable surgical lesion is present.³⁷

Whether the patient's complaints are acute, subacute or chronic, the prevention of ongoing chronic disability is the overriding goal. Therefore, rapid transition from more passive forms of care to more active forms are instituted as quickly as possible.

CONCLUSION

The approach to LBP presented here is based on the attempt to rapidly reduce pain, improve function, and prevent chronic disability. This requires a focused, aggressive approach to evaluation and management that is designed to identify the key factors producing pain and the potential for disability, and quickly address these factors for early resolution. It often requires a team-oriented, multidisciplinary approach. This will ultimately prove to be of benefit to patients as well as society as a whole.

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Physicians in Rhode Island

Leslie Tucker, Nisha Lodhavia and David Terreault

This report summarizes findings from a 1999 physician survey sponsored by the Governor's Advisory Council on Health. The survey instrument was designed in collaboration with the Rhode Island Medical Society, the Rhode Island Department of Health, and the Brown University Public Health program. Over half (52%) of Rhode Island physicians responded, with a distribution of respondents that mirrored the state's distribution of physicians.

THE NATIONAL CONTEXT

Physician services are the second largest component of national health care spending. Physicians' share of health spending has hovered between 18% and 23% for the last three decades.¹ More significantly, physicians' clinical decisions about the type and place of treatment, the tests to order, and the required intensity of services, drive almost 80% of all health care spending.

RHODE ISLAND PHYSICIAN SUPPLY

As of December, 1999, there were approximately 3,643 physicians licensed to practice in Rhode Island, of

whom 2,714 were active and cited Rhode Island as their primary practice location. Of these, 2,424 physicians provided direct primary and specialty patient care at least 20 hours per week.²

Approximately 70% of the state's total physician workforce is located in the Providence area.³ However, among the 929 Rhode Island licensees whose main practice location is outside the State are physicians in neighboring Massachusetts, Connecticut, and popular vacation destinations such as Florida. An increasing number of physicians who provide remote consultation and those who work in administrative/medical review positions for large firms also are licensed here. For example, Rhode Island's complement of licensees includes a radiologist who reads digitally transmitted x-rays in Georgia - testimony to the impact of new information technology and "telemedicine" on the practice of medicine.

Rhode Island ranks 6th in the nation in its supply of licensed physicians relative to the size of its population.⁴ Nationally, the licensed physician to population ratio is 276 physicians per 100,000 civilian population. In Rhode Island the ratio is 354/100,000 civil-

Abbreviations Used:

AMA	American Medical Association
NAMCS	National Ambulatory Medical Care Survey
PHO	Physician-Hospital Organizations
RAPR	radiologists, anesthesiologists, pathologists, and rehabilitation specialists

ians. In comparison, Massachusetts, which ranks second, has a physician to population ratio of 434 physicians per 100,000 civilians. Connecticut, which ranks 5th, has a ratio of 380/100,000.⁵ As shown in Figure 1, the supply of physicians is increasing faster than the population overall, both nationally and in Rhode Island. [The comparative chart tracks licensed physicians in Rhode Island and nationally. That cohort includes retired and semi-retired physicians.]

Although physician-to-population ratios may suggest physician availability or shortage, they do not constitute a solid measure of the quantity or quality of health care received by the public. For example, Rhode Island's much higher than average physician-to-population ratio may be due to this state's larger proportion of small, independent practices, hospital-based subspecialists (especially internal medicine physicians) and academic/partial FTE-patient care physicians.

Rhode Island maintains a higher proportion (21%) of internal medicine physicians than the national average (15%). Rhode Island also has a slightly higher proportion of pediatricians, psychiatrists, and emergency room physicians than the rest of the United States. On the other hand, Rhode Island has a lower percentage of family physicians and general surgeons.⁶ (Figure 2)

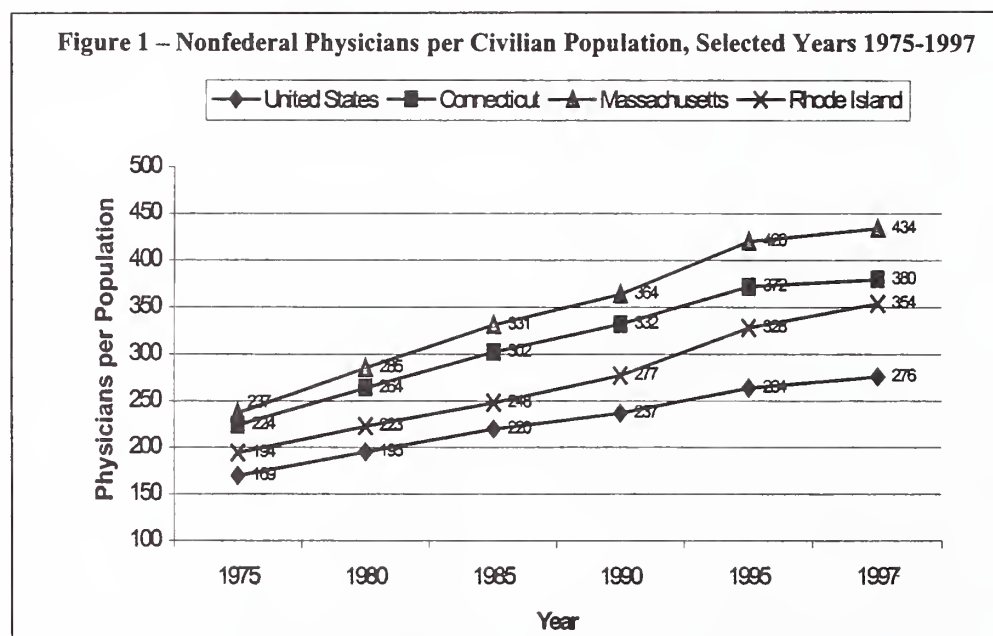


Figure 1. National Physicians per Civilian Population, Selected Years 1975-97.

Source: American Medical Association.

Figure 2 - Percentage of Physicians by Specialty, Rhode Island and U.S.

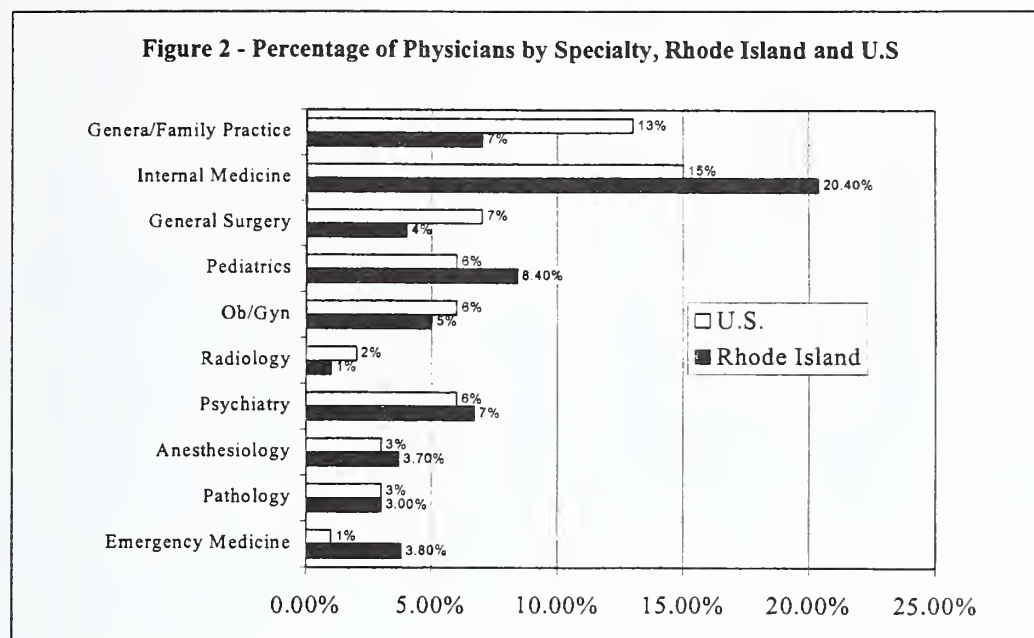


Figure 2. Percentage of Physicians by Specialty, Rhode Island and US, 1998

Source: American Medical Association, *Physician Characteristics and Distribution in the U.S.*, 1999; and DOH Medical Licensure Database, 1999

PRIMARY CARE

The primary care specialties include Family Practice/General Practice, General Internal Medicine, and General Pediatrics. As of December 1999, there were 1226 physicians in these specialties actively practicing in Rhode Island.⁷ These physicians represent 51% of all Rhode Island physicians active in patient care, and equate to 1 primary care physician for every 814 people. However, large proportions of both internists and pediatricians actually are in subspecialty practice. Counting only those internists and pediatricians who have no secondary specialty reduces the number of primary care internists by nearly half (from 727 to 335) and the number of primary care pediatricians by over a third (from 255 to 166). The combined total primary care physician supply then drops to 704, or 30% of all actively practicing physicians. The resulting ratio of primary care physicians to population changes to 1:1418. This ratio is still slightly higher than the population-based requirement estimate derived from physician workforce planning models.

In addition to the primary care specialties, obstetricians/gynecologists may serve as primary care physicians for their patients. In 1999, 140 ob/gyns were actively practicing in Rhode Island; 124 of them were not certified in a subspecialty field.

Finally, subspecialty physicians contribute to primary care capacity. In the most recent National Ambulatory Medical Care Survey,⁸ physicians in surgical and non-surgical specialties reported that for approximately 20% of all office visits, they considered themselves the patient's primary care physicians.

From 1997 to 1999, the number of actively practicing PCPs in Rhode Island increased by a net 61 physicians (31 FP/GP; 12 IM; 18 PEDs). The state gained a net of 5 ob/gyns.

PRACTICE SIZE AND ORGANIZATION

More than a quarter (27%) of RI physicians reported being in solo practice. Half (52.4%) practiced in groups

of 4 or fewer; 10% in a 2-physician practice, and 9% in a 3-physician practice. Three quarters (76.9%) of all RI physicians practiced in groups of 10 or fewer. Just 15% reported practicing in groups larger than 20.

Older physicians are more likely to persist in solo practice, with nearly half those age 55 and over practicing in such settings. However, as these physicians retire from the workforce, they are being replaced by younger doctors who prefer a less entrepreneurial, more predictable and collectivized practice environment.

Compared to the rest of the nation, Rhode Island physicians have been slow to organize into practice arrangements that have real market leverage.

As of December, 1999, nearly half of all RI physicians (46.9%) belonged to Independent Practice Associations (IPAs), and 70% belonged to Physician-Hospital Organizations.

However, despite the growing membership in these collectivized arrangements, physicians do not appear to attach great importance to them for purposes of strengthening their practices. Nearly two thirds of all physicians believe that membership in an IPA is not important to maintaining their panel of patients (63%); recruiting new patients (68%); protecting their fees (55%) or negotiating better fees (54%) (Figures 3, 4).

Surgeons and psychiatrists appeared to place the least value on IPA membership. Slightly more than half

Figure 3 - Is Membership in an IPA Important for Recruiting New Patients?

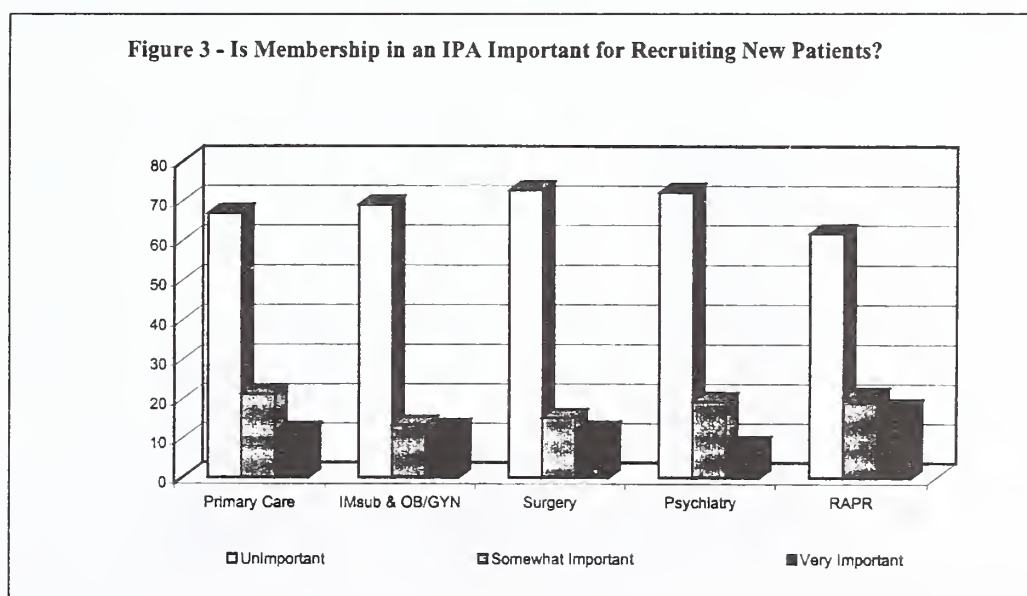


Figure 3. Is Membership in an IPA Important for Recruiting New Patients?

Source: 1999 Physician Survey

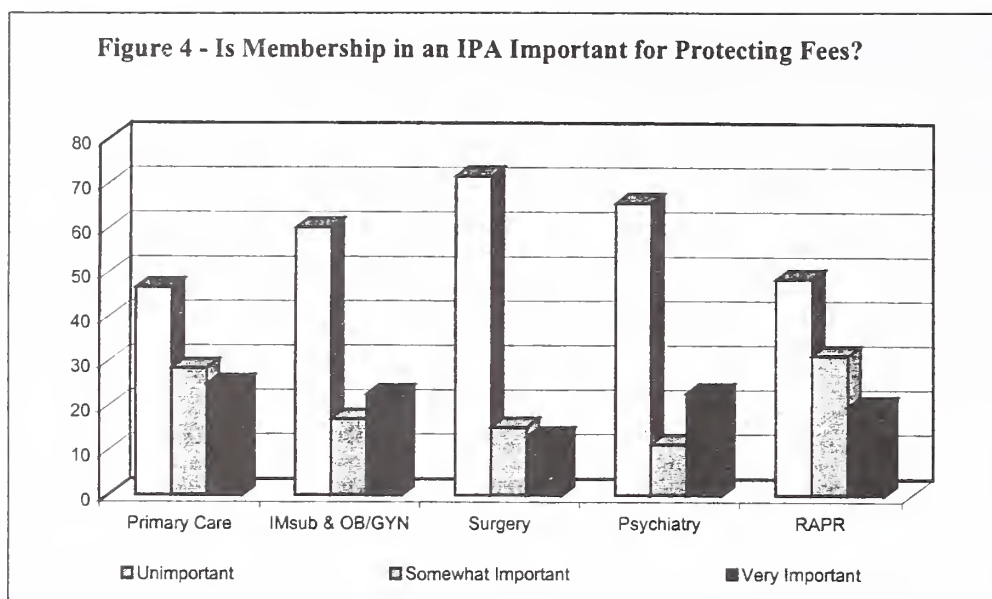


Figure 4. Is Membership in an IPA Important for Protecting Fees?

Source: 1999 Physician Survey

of primary care physicians believed that membership in an IPA was somewhat or very important to protecting fees or negotiating better rates. Whether these results suggest that physicians had other reasons for joining IPA organizations or that the organizations failed to achieve hoped-for gains for physicians is not clear.

Physician valuation of membership in Physician-Hospital Organizations (PHOs) followed a similar pattern. A substantial majority of physicians reported membership in one or more PHOs; but more than 2/3 (68%) believed that membership in a PHO was unimportant to maintaining their patient base; 72% believed it unimportant to recruiting new patients, and 62% believed it unimportant to protecting or negotiating better fees.

PATIENT LOAD

A physician's number of patients can fluctuate according to several factors. Higher rates of insurance coverage generally correspond to higher numbers of physician visits, while limited coverage corresponds to fewer visits. Changes in the rate of hospital inpatient and outpatient utilization can shift patient care visits among different specialties. Changes in the supply of or referral patterns to physicians within a particular specialty could increase or decrease local competition for patients within that specialty.

Physicians were surveyed regarding changes in their patient volume over the past two years: 61% of RI physician said that their patient volume increased; 12% said it decreased, and 27% perceived no change. (Figure 5)

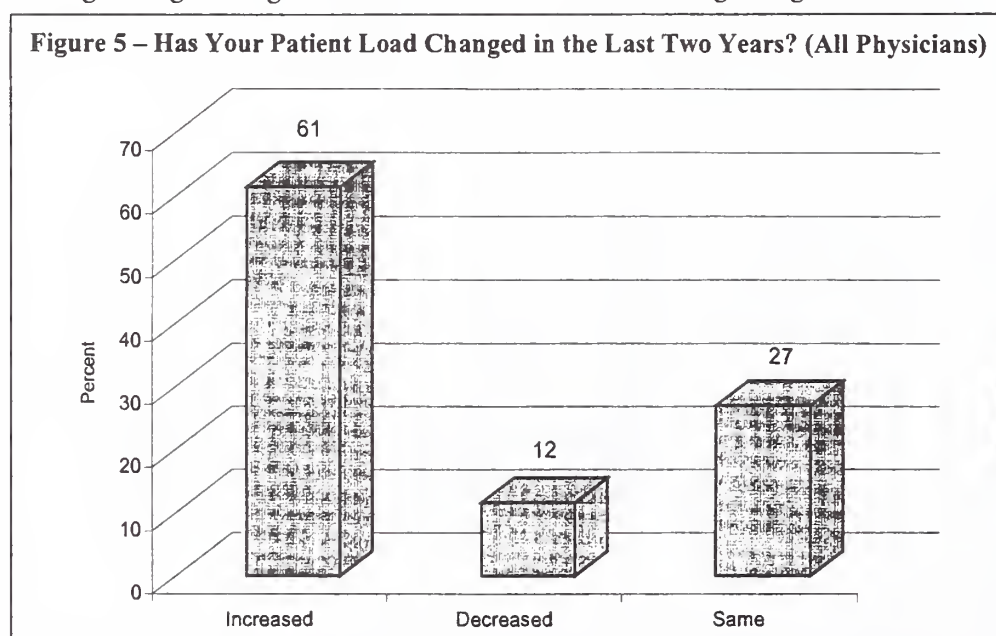


Figure 5. Has Your Patient Load Changed in the Last 2 Years?

Source: 1999 Physician Survey

By specialty, hospital-based RAPR physicians (radiologists, anesthesiologists, pathologists, and rehabilitation specialists) were most likely to report increases in patient volume (70%). Surgeons (16.5%) and psychiatrists (16.3%) were the specialists most likely to report decreases in patient volume.

Physicians were also asked their perceptions of the level of same-specialty competition for patients in their local communities. Surgeons were significantly more likely to report high levels of competition (52%); psychiatrists were least likely to do so (11.7%).

EMPLOYMENT

Rhode Island physicians were more likely than their national colleagues to be independent contractors or salaried practice employees rather than practice owners. Fewer than half (45%) of Rhode Island physicians reported an ownership interest in their practice, compared to 62% nationally. Fifty-four percent of Rhode Island physicians were practice employees, compared to 36% nationally. Nine percent of Rhode Island physicians, compared to 2% nationally, were self-described independent contractors.

An increasing number of physicians were seeking the defined work schedules and relative freedom from practice administration and overhead expense-sharing offered by salaried, employed positions. In particular, young physicians and those newly entering practice or new markets sought the security of these positions from which to build a practice base.

In addition to group practices, a number of Rhode Island physicians held salaried positions in hospitals, universities, and government health programs.

REIMBURSEMENT

Overall, the largest portion of Rhode Island physician revenue (51%) came from private insurance. Medicare and Medicaid represented 22% and 18% of revenue, respectively. Patient out-of-pocket spending and other sources accounted for 13%.⁹ These are "average" figures; the actual distribution

Figure 6 - What Were You Reimbursed per Visit (99203) by These Plans?

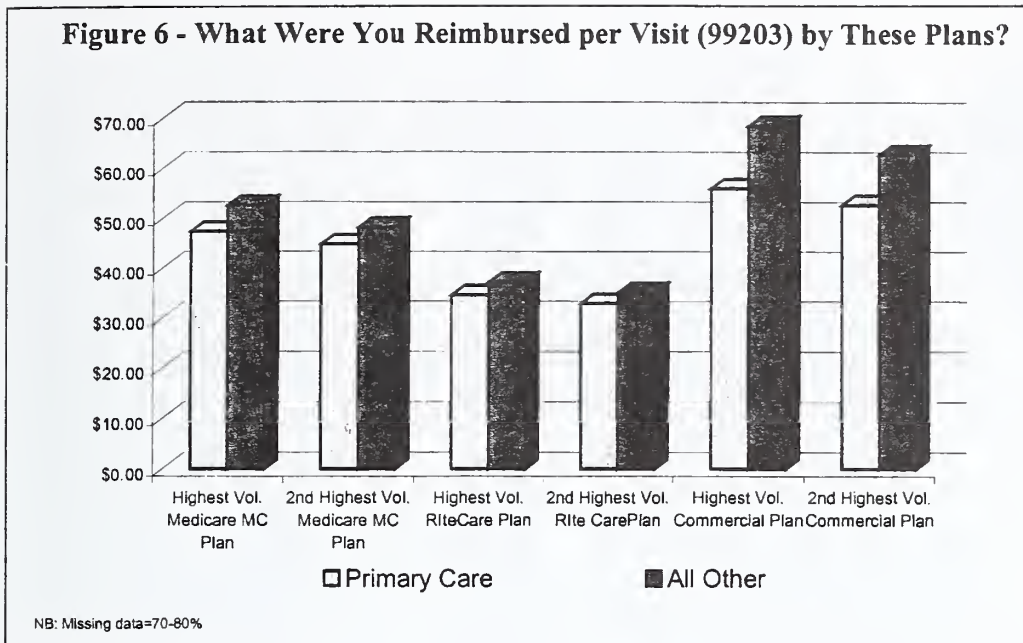


Figure 6. reimbursement for office visit code (99203)
Source: 1999 Physician Survey

of physician revenue sources varies by physician specialty. For example, pediatric practices have a smaller share of Medicare revenue and a greater share of Medicaid revenue than the average practice.

National surveys of physician practices indicate that the New England region, and Massachusetts in particular, rank just behind New York and California for the highest office visit fees in the nation. Medicare fee schedule payments for physician services are 4% to 7% lower per service in Rhode Island than in Massachusetts. Physician reimbursement under commercial and Medicare risk contracts for the most common adult medicine visits/procedures varies between Rhode Island, Massachusetts, and Connecticut with no evident pattern.

Almost all physicians (98%) participate in some form of managed care - most in Preferred Provider Organizations (PPOs) or other arrangements in which compensation is based on reduced fee-for-service reimbursement rather than on shared financial risk for services delivered to the managed care population. However, this is beginning to change, as a number of RI physicians reported participating in risk-sharing arrangements under Medicare managed care plans. On average, of those physicians (20%) who had a portion of their income at risk, the majority reported that they had between 1%

to 25% on the line.

Physician reimbursement for visits and procedures varied tremendously by specialty and by payor. Medicare and Medicaid fee-for-service payments rates are determined by the federal and state government, respectively; private payer rates and Medicare and Medicaid managed care rates are set by health plans. Some plans make global capitation payments to physicians to manage virtually all costs of an individual enrollee's care, including hospital and prescription drug use. [For example, BlueCHIP has recently completed global capitation contracts with physicians in the state's two largest IPAs to manage Medicare Managed Care enrollees.]

Physicians were asked their level of reimbursement for a common office visit code (99203). For their highest volume plans, physicians reported that the mean commercial health plan payment was higher than the mean Medicare or Rite Care payment amount for that code. Within each of these payer categories, primary care physicians reported mean payment amounts roughly 10% lower than other specialties. (Figure 6)

Half of physicians reported an increase of the past two years in the number of patients who did not pay their bills (a combination of uninsured patients who did not pay, and insured patients who did not pay their co-pay-

ment or deductible). About 2% reported a decrease, with primary care physicians most likely to do so (7%). Slightly more than 40% of physicians perceived no change in the number of patients for whom they provided charity care.

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5. Physician Characteristics and Distribution in the U.S., 1999, American Medical Association.
6. Physician Characteristics and Distribution in the US, 1999, American Medical Association, and Rhode Island Medical Licensure Database, 1999.
7. Includes Ob/Gyn, FP/GP, Internal Medicine, and Pediatrician physicians who provide at least 20 hours of patient care per week.
8. National Ambulatory Medical Care Survey, Centers for Disease Control, Advance Data No. 305, May 20, 1999.
9. Harvey Zimmerman, 1999.

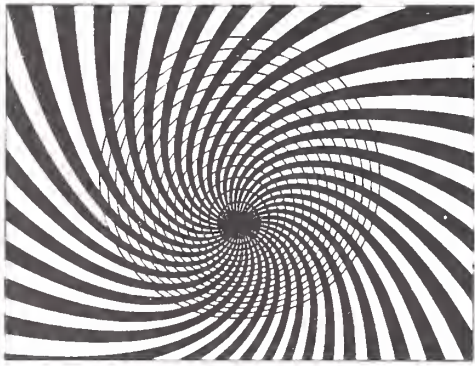
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IMAGES IN MEDICINE



Bone Metastases



Hussam Hamdalla, MD, and Robert J. Fram, MD

A 60 year-old man presented with 80 pound weight loss and pain in the right knee and back. Evaluation revealed widely metastatic small cell carcinoma of the lung. Although the bone scan demonstrated metastases to both humeri and femurs, it did not show disease in the spine (Figure 1). MRI of the spine (Figures 2 and 3) revealed diffuse metastases to multiple vertebra, epidural metastases

Abbreviations Used:

MRI magnetic resonance imaging

at D9, L3-5, and a right paravertebral mass at L3-4. Increased uptake on bone scans is affected by osteoblastic activity. False negative bone scans may occur when there is purely lytic disease as is common in multiple myeloma as well as in the presence of significant bony destruction and rapidly growing lesions.¹

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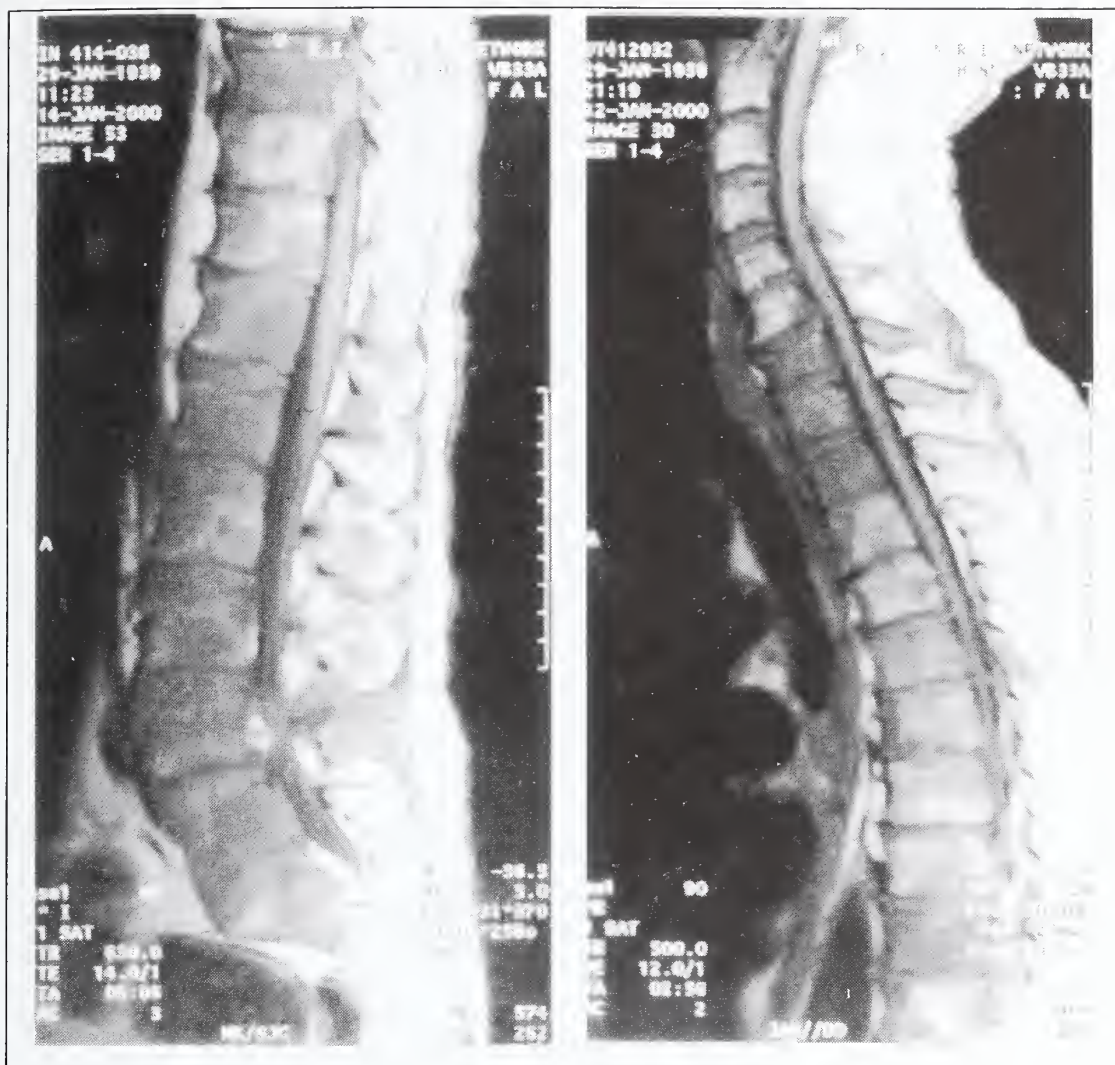
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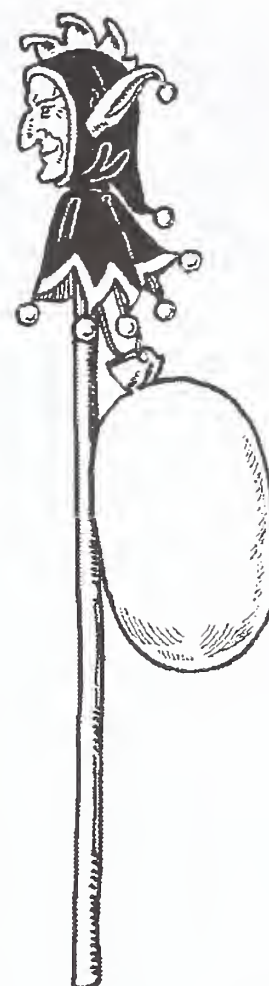


Figure 1.





Figures 2 and 3.



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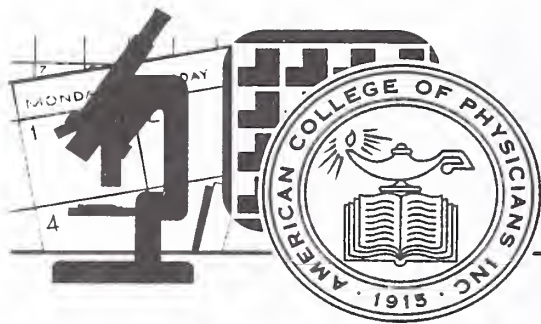
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THE CREATIVE CLINICIAN: CASE OF THE MONTH

"The practice of medicine is an art, not a trade; a calling, not a business ..." — WILLIAM OSLER, Aequanimitas

Editor: Anthony Mega, MD; Co-editor: Fred J. Schiffman, MD



Spinal Surgery for Severe Scoliosis in Parkinson's Disease



Rowena Emilia J. Tabamo, MD, Hubert H. Fernandez, MD, Joseph H. Friedman, MD, Phillip R. Lucas, MD

The incidence of scoliosis in Parkinson's Disease (PD) patients is higher than in the geriatric population¹ and may be severe. Treatment modalities for idiopathic scoliosis include physiotherapy, orthotic management, electrical stimulation techniques and surgery.² Anti-PD medications are often not helpful. A definitive management for scoliosis in PD patients has not been reported.

We describe, what we believe, is the first case report of kyphoscoliosis aggravated by PD with significant improvement after surgery.

CASE REPORT

A 73 year old woman with a history of scoliosis in her twenties presented with a resting tremor of the left hand at age 62. She was diagnosed with PD with an initial im-

provement on levodopa. Four years later, she developed gradual worsening of her

kyphoscoliosis causing her to lean forward and to the right, resulting in postural instability and subsequently required a walker for ambulation despite adjustments of her anti-PD medications. Six years later, she had poor balance control even while sitting and had difficulty standing or walking unassisted (UPDRS motor score of 52; Hoehn and Yahr stage 4). Her kyphoscoliosis progressed so that her right breast touched her thighs. Baseline radiographs were obtained. (Figure A). Due to her increasing disability and discomfort, she underwent a two-step surgical spine procedure—an anterior decompression and fusion (anterior spinal release and discectomy with interbody fusion using rib graft and Harms cages) and posterior instrumentation and fusion with placement of Isola rods. Anti-PD medications then were: carbidopa/levodopa 25/100 mg every 2 to 2.5 hours, pramipexole, 0.5 mg three times per day and amantadine 100 mg twice a day.

Five months after surgery, her balance, posture and gait had significantly improved with lesser dependence on the walker and greater mobility with bending. However, in a follow up telephone interview thirteen months later, she related a slight tendency to list towards the right again. Her current medications include ropinirole 4mg three times per day and carbidopa/levodopa 25/100 mg tablet five times per day.

DISCUSSION

Disturbance in central and peripheral postural control mechanisms has been implicated in idiopathic scoliosis.³ The dopaminergic system defect seen in PD may contribute to the postural dysfunction aggravating scoliosis.⁴ It has been suggested that a significant correlation exists between the spine deviation and the laterality of Parkinsonian manifestations,^{1,5} although we have seen patients with relatively symmetric disease who developed severe kyphoscoliosis after onset of PD.

Abbreviations Used:

PD	Parkinson's Disease
UPDRS	Unified Parkinson's Disease Rating Scale

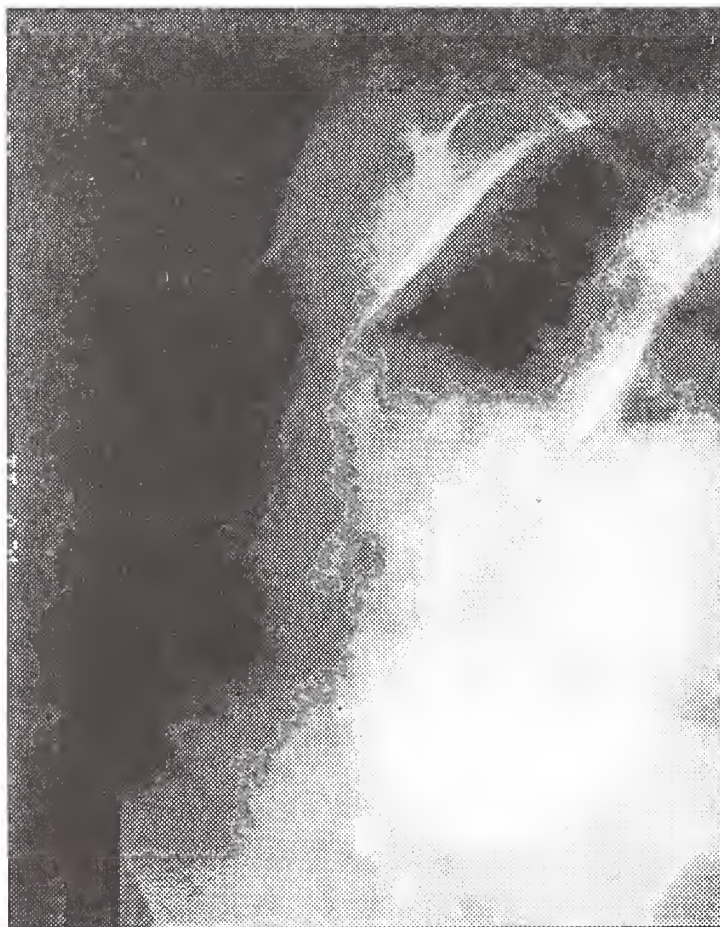


Figure A. Anteroposterior view of the thoracolumbar spine prior to spinal surgery showing a Cobb angle of 45 degrees from T5-L4.

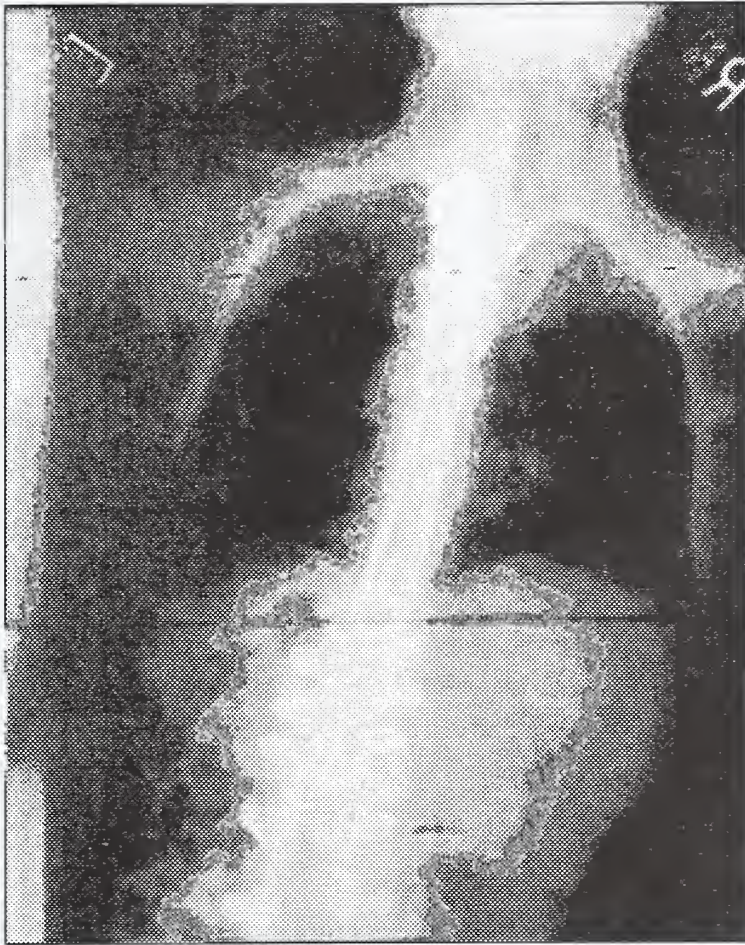


Figure B. Anteroposterior view after spinal instrumentation using Isola rods showing improvement of scoliosis with a Cobb angle of 15 degrees.

Spinal surgery has not been described as a treatment for scoliosis in PD patients. Since postural dyscontrol mechanisms persist in PD, the natural history of scoliosis remains unclear. Moreover, the asymmetric paraspinal muscle tensions from PD causing or aggravating scoliosis may eventually cause surgical repair to be ineffective. Nonetheless, this patient who had significant disability from her kyphoscoliosis and PD showed marked improvement after spinal surgery. (Figure B). Her Cobb angle from T5 to L4 corrected from 45 to 15 degrees. Her decompensation improved from 16 centimeters off center to 4 centimeters. Her kyphosis angle of 90 degrees improved to 45 degrees (normal). Although the overall long-term efficacy of spinal surgery is unknown, it is a serious consideration for patients who have significant disability from scoliosis aggravated by PD and should be studied.

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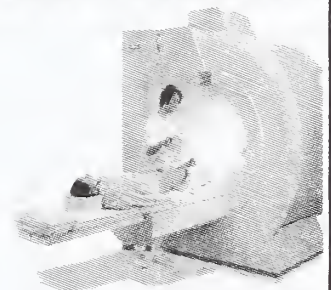
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A Resource for the Primary Care Physician

Raymond B. Maxim, MD

In previous columns I mentioned that Rhode Island Quality Partners (RIQP) will be concentrating its efforts in the outpatient arena, focusing on diabetes, adult immunizations and breast cancer screening. It is clear in the literature that improved performance in each of these areas leads to better patient outcomes. While we are doing well with some of the interventions in the three focus areas, there is still considerable room for improvement. I would like to share RIQP's approach to each of these areas now that we have a more clearly defined plan.

DIABETES

Diabetes is an important focus for two reasons - its impact on the lives of Medicare beneficiaries and its costs to the healthcare system. RIQP's charge is to improve patient care as it relates to three specific indicators: measurement of hemoglobin A_{1c}, dilated fundoscopic exams, and measurement of a lipid profile. Records for each are available from administrative data sources (i.e. billing records), thus do not require chart abstraction.

There is strong evidence that better glucose control and surveillance for end organ complications improve outcomes, and the body of evidence is growing. The Diabetes Control and Complications Trial (DCCT)¹ and the United Kingdom Prospective Diabetes Study (UKPDS)² both demonstrated a strong correlation between glucose control and microvascular disease. The most interesting fact to come out of the UKPDS is that for every 1% re-

duction in hemoglobin A_{1c}, there is a 35% reduction in risk for microvascular complications.³ Despite advances in diabetes treatment, it still remains the number one cause of blindness in adults.⁴ When appropriate, screening and photocoagulation can reduce the frequency and severity of debilitating vision loss in diabetic patients.

Diabetic patients also have a two-to-four increased risk of cardiovascular disease, warranting aggressive treatment of cardiovascular risk factors. This includes measuring lipids and treating dyslipidemias following the guidelines suggested by the National Cholesterol Education Program (NCEP).^{5,6}

For the past two years, RIQP has been providing Rhode Island's physicians with individualized data for benchmarking. In the next several weeks, we will send you personalized data on the diabetes indicators. Diabetic patients will be identified by ICD-9 codes and by the number of visits to your office. You will be credited for any services a patient receives, even if it is from another provider. This is particularly important with dilated eye exams. As always, this data is for personal benchmarking only and will not be shared with anyone.

You may remember hearing or reading about the DEARS program in previous RIQP columns.^{7,8} The Diabetes Education, Assessment, Referral and Screening (DEARS) program consists of a traveling, multidisciplinary team which provides all the laboratory

Abbreviations Used:

DCCT	Diabetes Control and Complications Trial
DEARS	Diabetes Education, Assessment, Referral and Screening
NCEP	National Cholesterol Education Program
PRO	Peer Review Organization
RIQP	Rhode Island Quality Partners
UKDPS	United Kingdom Prospective Diabetes Study

work and counseling needed for good diabetes care. The program is arranged at your office, or at a convenient location. My personal experience with DEARS has been terrific. Please let us know if you are interested in this exceptional program.

The PRO community has learned that in order for our interventions to be successful, they must engage the Medicare beneficiaries. Consequently, you may be receiving requests from your patients to sign our preventive health checklist, which includes recommended cardiovascular, diabetic and cancer screening exams. The checklist was widely publicized in several prominent beneficiary publications during the past few months. Other beneficiary interventions we are planning include directed reminders for screening tests, along with a media campaign designed to raise general awareness of preventive screening exams.

MAMMOGRAPHY

Mammography screening remains an important focus for RIQP. Overall,

there is an improvement in the delivery of this Medicare covered benefit to Rhode Island women. However, less than half of all of the state's Medicare-enrolled women receive this potentially life-saving service annually. We are working closely with the American Cancer Society, the Rhode Island Breast Cancer Coalition, the Rhode Island Commission on Women, the Rhode Island Department of Health and others within the breast cancer community to get across the message that early detection and treatment provide women with the best opportunity to survive breast cancer. Our activities with these groups are particularly rewarding because of the degree of dedication and hard work they put into these efforts. One of the projects we are involved in with them will provide trained volunteers to speak about mammography at local libraries. We will also be working with church groups to encourage their members to have mammograms.

You should have received your personalized rates for mammography by now. Benchmarking will be a large part of our campaign this year. It is important to remember that you are the single, most important determining factor in whether or not your patients get a mammogram. If you tell your patients to get a mammogram, they will. If a woman declines, you must continue to remind her of the importance of having a mammogram each time she comes to see you. Like other behavior change, getting her to overcome her fear or misconceptions is a process which takes patience and persistence. While not every woman will change her mind, the effort is worth it for those who do.

IMMUNIZATION

Each year state performance in adult immunization improves. Last flu season was no exception, thanks in part to the Ocean State Adult Immunization Coalition's successful campaign. While the bulging emergency departments, overcrowded wards, and frantic phone calls from patients with flu-like illness during the just-completed season are still fresh in your mind, please remember to immunize your adult patients with pneumococcal and influenza vaccines. Many of the admissions and deaths of this past season may have been avoided had people been properly immunized.

An adult immunization record is just as important as a childhood record. There are several versions available through RIQP, which we would be happy to provide. We also have preventive health records which include immunizations that are available for your patients to keep with them. This may be very helpful for the "snowbirds" who receive out-of-state care during the winter months. Meanwhile, data that will provide individual rates of immunization are currently being compiled and will be sent to you before the start of the next flu season.

ACADEMIC DETAILING

Taking a page out of the pharmaceutical companies' playbook, academic detailing has become a new phrase in the quality improvement lexicon. But it is not the academic

detailing with which you are familiar, when a company representative tries to detail you on their newest drug. Instead, RIQP staff members will be visiting physicians to "sell" the preventive measures discussed above. Because physicians agree on the need for preventive medicine, especially services which have a good evidence base, I think very little actual selling will need to take place. The goal and challenge are to find ways to integrate these measures into already busy practices and to share methods we know are successful, keeping in mind that each office is different in scope of practice and culture. What works well in one office may not work at all in another. We are cognizant of your need to work within your practice and not change the practice to fit some ideal.

Finally, I want to mention TAKE CARE Rhode Island, a coalition of the major stakeholders in Rhode Island healthcare. The coalition was announced at a press conference in February. It enjoys the support of state government, the health plans, hospitals, professional associations and community groups. The goal is to provide a single, unified message about essential aspects of care. Initially, the coalition's focus will be on hospital care. Some examples of the inpatient processes of care are beta-blocker and aspirin use following myocardial infarction and the use of ACE inhibitors in congestive heart failure. Because hospitalization is a short portion of a patient's lifetime, the progression to include outpatient processes of care is a natural one for the coalition. I expect TAKE CARE Rhode Island to be a big part of RIQP's effort to improve the quality of care in Rhode Island.

Please contact us if you have any questions or comments about anything discussed in this article, or if you would like to share any solutions to quality problems. Your feedback is always appreciated.

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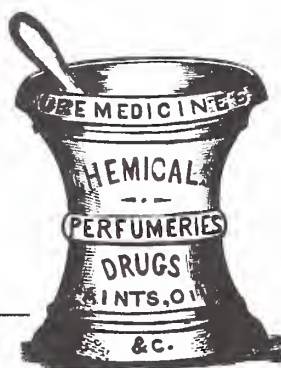
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Advances in Pharmacology

The Thiazolidinediones or "Glitazones" A Treatment Option for Type 2 Diabetes Mellitus

Mary Newbold Brown, RPh

Type 2 diabetes mellitus is a chronic illness that results from defects in both insulin secretion and insulin action. The successful management of type 2 diabetes relies on following the American Diabetes Association (ADA) recommendations on diet and exercise most recently updated in January 2000.¹ When diet and exercise do not achieve the desired glycemic control, drug therapy is required. Oral agents traditionally had been limited to sulfonylureas, which increase insulin secretion from the pancreas. More recently, metformin was introduced. It acts by increasing peripheral insulin sensitivity and suppressing endogenous glucose output. The thiazolidinediones or "glitazones" are a new class of drugs available to treat type 2 diabetes. Thiazolidinediones decrease insulin resistance and are only effective in the presence of insulin. Metformin and the glitazones have an advantage over the sulfonylureas in that they do not cause hypoglycemia. The thiazolidinediones are selective agonists for the nuclear peroxisome proliferator-activated receptors (PPARs). These receptors are found in key sites for insulin activity including adipose tissue, skeletal muscle, and the liver and are involved in the control of glucose production, transport and utilization. Currently, three thiazolidinediones are available. (Table 1)

TROGLITAZONE (REZULIN®)

Troglitazone, the first agent in this class, was introduced in January 1997 as monotherapy or combination therapy

Rezulin® was taken off the market on March 21, 2000. The risk of liver toxicity is too high compared to other agents in its class. The FDA has received reports of 60 deaths linked to troglitazone

Abbreviations Used:

ADA	American Diabetes Association
ALT	alanine amino transferase
FPG	fasting plasma glucose
PPAR	peroxisome proliferator-activated receptor

for the treatment of type 2 diabetes. In clinical trials troglitazone reduced HbA_{1C} when used in combination with either insulin or sulfonylureas. In one 6 month, double blind, placebo-controlled study in insulin treated patients with type 2 diabetes at baseline patients were receiving a mean dose of 73 units of insulin daily and had a mean HbA_{1C} of 9.42%. In total, 350 patients were randomized to receive 200mg or 600mg troglitazone per day or placebo. At the end of the study patients in the 200mg and 600mg troglitazone groups had a 0.7% and 1.3% reduction in HbA_{1C} and 36mg/dl and 50mg/dl reductions in fasting plasma glucose (FPG), respectively. In addition the insulin dose was reduced by 11% in the 200mg troglitazone group and 29% in the 600mg troglitazone group compared to a 1% increase in the placebo group.² Troglitazone has also been reported to have a synergistic effect when used concomitantly with a sulfonylurea. In a 52 week, double blind, placebo controlled study in 522 patients with type 2 diabetes who had not achieved glycemic control on maximal dose sulfonylurea, the combination of troglitazone and micronized glyburide reduced FPG and HbA_{1C} more than either agent alone.³

Troglitazone may induce drug metabolism by CYP3A4, one of the major isoenzymes of the cytochrome P-450 (CYP-

450) system. These enzymes exist predominantly in the liver; awareness of these isoenzymes and their substrates and inducers aid in the prediction of drug interactions.⁴ Consider this when prescribing troglitazone with CYP substrates such as dihydropyridine calcium channel blockers, cisapride, corticosteroids, cyclosporine, and statins.

Plasma volume increased by 6% - 8% in many patients taking troglitazone so that caution must be taken in patients subject to congestive heart failure. Although serum cholesterol increased slightly during troglitazone therapy, the ratio of LDL to HDL generally remained constant.⁵ Post marketing, concern was raised due to reports of liver failure. According to the FDA by June 1999, 43 patients had developed liver failure after initiating troglitazone therapy. Troglitazone was the likely cause in 38 of those cases although in the controlled trials liver toxicity was not significant. Twenty-eight of these patients have died, seven survived following liver transplant, five survived without transplant and the outcome in three cases is undetermined.⁶ On June 16, 1999 the monotherapy indication was withdrawn by the FDA due to the risk of liver failure.⁸ Currently, troglitazone is approved for combination therapy with a sulfonylurea, metformin, or insulin for patients with type 2 diabetes not adequately controlled by these drugs alone. Patients on troglitazone therapy should have LFTs prior to initiating therapy, monthly for the first year, and quarterly thereafter. Troglitazone should be avoided in patients with a history of alcohol abuse or liver disease.

ROSIGLITAZONE (AVANDIA®)

Rosiglitazone, the second thiazolidinedione marketed in the US, was approved by the FDA on May 25, 1999, for the treatment of type 2 diabetes either alone or in combination with metformin. In clinical trials involving more than 4,600 people with type 2 diabetes rosiglitazone lowered blood glucose without significant side effects. Compared to placebo, rosiglitazone reduced mean fasting plasma glucose (FPG) by 31 - 76mg/dl and HbA_{1c} by 0.8 - 1.5%. In combination with metformin, rosiglitazone reduced FPG by 40 - 56mg/dl and HbA_{1c} by 0.8 - 1.2% compared to metformin alone.⁹ Like troglitazone,

rosiglitazone is associated with weight gain, approximately 6.6 - 9.9 pounds in clinical trials and also with mild edema. Rosiglitazone also increased LDL and HDL cholesterol by 12% and 18% respectively, but the LDL/ HDL ratio remained the same. Adverse reactions were mild to moderate in severity and usually did not require discontinuation of treatment.⁷

The glitazones offer a promising alternative to patients not currently able to achieve target glycemic control with current therapy.



Unlike troglitazone current evidence from clinical trials suggests that rosiglitazone is not associated with liver toxicity. Elevations in ALT greater than three times the upper limit of normal occurred in 0.2% of both the rosiglitazone and placebo groups and 0.5% of patients treated with active comparators, including metformin and sulfonylureas.⁷ Due to the problems associated with troglitazone and the lack of substantial post marketing data, monitoring liver function tests is recommended for patients on rosiglitazone therapy.

The recommendation is to obtain LFTs prior to initiating therapy, every two months for the first year, and periodically thereafter. This precaution may be well founded. Recently two cases of severe hepatocellular injury have been associated with rosiglitazone therapy.^{8,9} In both instances the patient had received rosiglitazone therapy for less than one month and the liver injury appeared idiosyncratic. Both patients recovered fully following the discontinuation of rosiglitazone.

PIOGLITAZONE (ACTOS™)

Pioglitazone is the newest thiazolidinedione, marketed

Table 1

	Troglitazone	Rosiglitazone	Pioglitazone
Indication	Treatment of type 2 diabetes in combination with a sulfonylurea or metformin for patients not adequately controlled on those drugs alone.	Treatment of type 2 diabetes either alone or in combination with metformin.	Treatment of type 2 diabetes either alone or in combination with metformin, insulin, or sulfonylureas.
Dosing	200mg - 600mg QD with a meal No dosage adjustment required in the elderly	4mg - 8mg QD or divided in 2 doses No dosage adjustment required in the elderly	alone: 30mg - 45mg QD combin: 15mg - 30mg QD No dosage adjustment required in the elderly
Adverse effects	Weight gain 5.8 - 13.1lbs, edema, and possible increase in ALT.	Weight gain 6.6 - 9.9lbs, edema, upper respiratory tract infection, and headache.	Weight gain, edema, respiratory tract infection, headache, sinusitis, sore throat and muscle pain.
Monitoring	LFTs prior to therapy start; every month for the 1 st year then quarterly.	LFTs prior to therapy start; every 2 months for the 1 st year then periodically.	LFTs prior to therapy start; every 2 months for the 1 st year then periodically.
Drug Interactions	Cholestyramine ↓ absorption of troglitazone by 70% ↓ efficacy of oral contraceptives ethinyl estradiol & norethindrone concentrations ↓ 30% Induces CYP450 3A4	Does not inhibit any of the CYP450 enzymes at clinically relevant concentrations.	CYP450 3A4 is partially responsible for the metabolism of pioglitazone no PK drug interaction studies have been conducted with other drugs metabolized by this enzyme.
Lipid effects	↑ LDL up to 13% ↑ HDL up to 16% ↓ triglycerides up to 26% ↑ in total cholesterol up to 5% No change in LDL/HDL ratio	↑ LDL up to 12% ↑ HDL up to 18% variable effect on triglycerides ↑ in total cholesterol No long term change in LDL/HDL ratio	No change in LDL ↑ HDL up to 13% no change in total cholesterol ↓ triglycerides up to 28%
Availability	200mg, 300mg, 400mg tablets	2mg, 4mg, 8mg tablets	15mg, 30mg, 45mg tablet
Cost (AWP) per 30 days	200mg - 600mg QD \$89 - \$179	4mg - 8mg QD \$75 - \$137	15mg - 45mg QD \$86 - 149
Self pay patient cost per 30 days	600mg per day (2 x 300mg) \$199.97	8mg per day \$146.51	45mg per day \$166.31

on July 16, 1999, as monotherapy or combination therapy with metformin, insulin, or sulfonylureas for treatment of type 2 diabetes. Pioglitazone was effective at reducing FPG and HbA_{1C} in clinical trials. In three randomized, double blind, placebo controlled studies of patients with type 2 diabetes, pioglitazone reduced HbA_{1C} by 1.0 - 1.6% and mean FPG by 39 - 65mg/dl compared to placebo.¹⁰ Three 16 week, randomized, double-blind, placebo controlled studies were conducted to evaluate pioglitazone in patients with type 2 diabetes who were inadequately controlled despite treatment with a sulfonylurea, metformin, or insulin. Compared with placebo, the addition of pioglitazone to a sulfonylurea reduced the mean HbA_{1C} by 0.9% and 1.3% and FPG by 39mg/dl and 58mg/dl for the 15mg and 30mg doses, respectively. In combination with metformin, the pioglitazone group had reductions of HbA_{1C} and FPG of 0.8% and 38mg/dl respectively compared to placebo. In combination with insulin, 15mg pioglitazone reduced HbA_{1C} and FPG by 0.7% and 35mg/dl respectively. The 30mg dose reduced HbA_{1C} and FPG by 1.0% and 49mg/dl respectively. Pioglitazone is partially metabolized by the cytochrome P450 system isoforms CYP2C8 and CYP3A4. In vivo human studies have not been conducted to investigate any induction of CYP3A4 by pioglitazone. In vitro, ketoconazole inhibited up to 85% of hepatic metabolism of pioglitazone.¹¹ Although no formal interaction studies are available, due to pioglitazone's metabolism in part by CYP3A4, caution is advised when prescribing substrates and /or inducers of the CYP450 system.

Overall pioglitazone was well tolerated in clinical trials involving over 3,700 people with diabetes. Like the other agents in this class pioglitazone affects lipids, the overall effect on the lipid profile is favorable. In clinical trials, triglycerides were reduced 5% - 26%, HDL increased 6% - 13%, and LDL level and total cholesterol remained the same. Current evidence from clinical trials suggests that pioglitazone is not associated with liver toxicity. Due to the problems associated with its predecessor troglitazone and the lack of substantial post marketing data, monitoring liver function is recommended. Patients receiving pioglitazone therapy should have LFTs obtained prior to initiating therapy, every two months for the first year, and periodically thereafter.

SUMMARY

The glitazones offer a promising alternative to patients not currently able to achieve target glycemic control with current therapy. Glitazones have a synergistic effect when combined with sulfonylureas and metformin and may have a favorable effect on the dyslipidemia experienced by patients with type 2 diabetes. The main concern with these agents is safety due to the hepatocellular injury experienced by several patients taking troglitazone. Although elevations in serum alanine amino transferase (ALT) concentrations more than three times normal occurred in 1.9% of patients on troglitazone in clinical trials, liver toxicity was not truly associated with this drug until post-marketing use by more than 600,000 people in the US. The onset of elevated ALT

is typically delayed. In the clinical trials only one patient experienced an elevation in the first month, the majority occurred between the third and seventh month.⁹ The glitazones should be avoided in patients with liver disease or a history of alcohol abuse. The mechanism of action for troglitazone-induced liver disease is unknown; consequently, identifying a particular subset of people as being at an increased risk for developing liver failure is difficult. Therefore, monitoring liver function is of critical importance. The newer agents rosiglitazone and pioglitazone may provide a safer alternative, however this question will remain unanswered until clinicians have access to substantially more post marketing surveillance data. The two recent cases of hepatocellular injury associated with rosiglitazone therapy further supports a cautious approach to utilization of these agents.

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Health by Numbers



Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Jay S. Buechner, PhD

Progress in the Early Identification of Breast Cancer, Rhode Island, 1987-1998

John P. Fulton, PhD, and Dorothy Darcy, AS, CTR

Identifying female breast cancer at early stages of disease is an essential goal of cancer control. Breast cancer is curable much of the time if diagnosed in the earliest stages of disease and treated promptly. Screening for breast cancer with clinical breast examination (CBE) and mammography is effective in identifying breast cancer at early stages of disease, and may reduce breast cancer mortality in a population thus screened.¹ Accordingly, the State of Rhode Island has officially adopted the guidelines for breast cancer screening presented in Table 1,² and, in collaboration with the federal government, has sponsored statewide breast cancer screening programs since 1987.

Methods

The Rhode Island Cancer Registry (RICR), based at the Rhode Island Department of Health and operated collaboratively with the Hospital Association of Rhode Island, monitors the stage distribution of female breast cancers, assessing trends and differentials. Stage of disease at diagnosis (summary stage) is a data element required in all reports of newly diagnosed breast cancer made to the RICR.

All cases of breast cancer reported to the RICR for Rhode Island residents diagnosed 1987-1998 were selected for study. Years of diagnosis and ages at diagnosis were

Abbreviations Used:

CBE	clinical breast examination
RICR	Rhode Island Cancer Registry
SEER	Surveillance, Epidemiology, and End Results
SES	socioeconomic status

grouped to facilitate analysis. Census tracts of residence were grouped according to indicators of socioeconomic status (SES) from the 1990 U.S. Census of Population, creating four ordinal categories of SES (poverty, low, medium, and high). This measure is "ecological" in the sense that it describes the population of a geographic area, not the particular person to which it is assigned in the present analysis, serving as a rough proxy for individual SES. Information on race is presented for whites and African Americans only, because the numbers of cases attributable to women of other races are very small.

Results

The distribution by stage of newly diagnosed breast cancers in Rhode Island is very similar to the distribution in areas surveyed by the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute (Figure 1). [Note that SEER omits *in situ* cases from the calculation of percentages by stage.]³

Mammography has increased the proportion of tumors found *in situ* in Rhode Island, from 9% in 1987-1990 to 12% in 1991-1994 to 15% in 1995-1998. The CBE is not considered to be sensitive enough to detect tumors this small, although some *in situ* tumors may be found serendipitously by mammography after a CBE has detected other suspicious lumps.

Table 1. RI Breast cancer screening recommendations²

- * For women without a family history of pre-menopausal breast cancer, clinical breast examination (CBE) should be performed at the periodic health examination after the age of 30.
- * Annual CBE and mammography after age 40.
- * For women with a first degree relative diagnosed with pre-menopausal breast cancer, annual mammography should commence 5-10 years prior to the age at which the relative was diagnosed.
- * Women with BRCA1 and BRCA2 mutations should commence monthly breast self-examination by 20 years of age, and should receive annual or semiannual CBE, and annual mammography, beginning at age 25 to 35 years.

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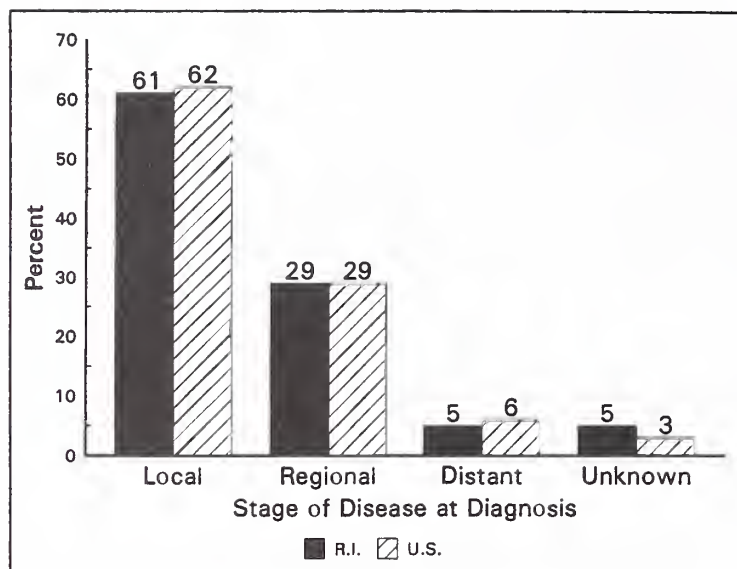


Figure 1. Invasive female breast cancers by stage of disease at diagnosis, Rhode Island and the United States, 1989-1995

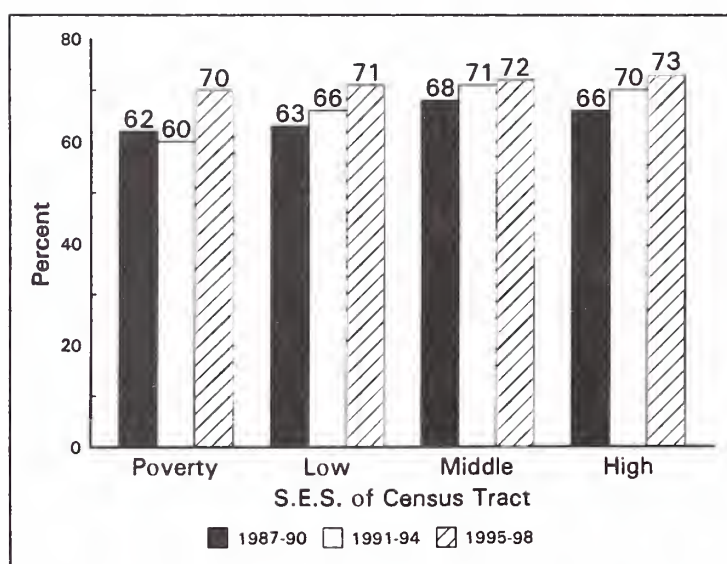


Figure 2. Percentage of female breast cancers staged in situ or localized, by socioeconomic status of census tract of residence and by year of diagnosis, Rhode Island

Socioeconomic differentials in early detection are small and getting smaller. The goal of breast cancer screening is to identify all tumors before they have spread regionally, because five-year survival is substantially higher for *in situ* and localized tumors than for tumors which have spread regionally or metastatically. The percentage of early-stage tumors increased statewide from 65% in 1987-1990 to 68% in 1991-1994 to 72% in 1995-1998 (Figure 2). Women residing in census tracts of all SES levels benefited, although small differentials favoring women residing in higher SES areas persisted throughout the 12 years of observation.



Race differentials are dramatic for the period of observation as a whole (Figure 3). The percentages of breast cancers detected at early stages of disease (*in situ* and localized) are much higher for whites than African Americans.

Race differentials are dramatic for the period of observation as a whole (Figure 3). The percentages of breast cancers detected at early stages of disease (*in situ* and localized) are much higher for whites than African Americans.

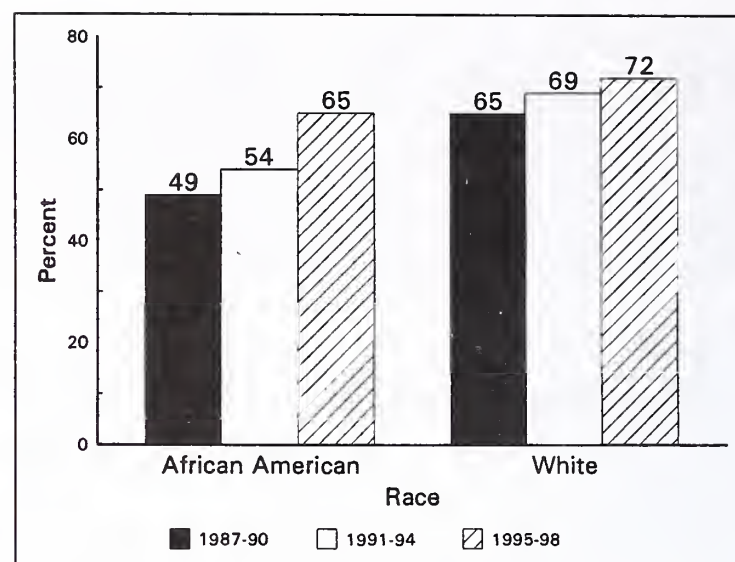


Figure 3. Percentage of female breast cancers staged in situ or localized, by race and by year of diagnosis, Rhode Island

This gap has lessened over time, however.

Discussion

To evaluate the overall effectiveness of breast cancer screening efforts in Rhode Island, the RICR routinely monitors reports of female breast cancers, focusing on the distribution of stage of disease at diagnosis over time and across demographic groups. Since 1987, the percentages of tumors found *in situ* and localized have increased. Women have benefited across SES and racial groups, and racial differentials have diminished. Systematic breast cancer screening has helped all Rhode Island women. We must continue this work, focussing on those groups of women who are at higher risk of being diagnosed with breast cancer at more advanced stages of disease.

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Bone Mineral Density Assessment

Susan G. Leffler, MD, and Jonathan P. Vaccaro, MD

[PART TWO OF A TWO-PART SERIES]

Osteoporosis is a common disease in Rhode Island. It affects about 34,500 women and 8,500 men. In addition, an estimated 64,800 women and 8,500 men in the State are believed to be osteopenic.¹

This second article in a two-part review of bone mineral density (BMD) assessment will focus on the interpretation of test results and recommended frequency for screening or monitoring. Part I described types of bone mineral testing and indications for their use.

OSTEOPOROSIS CLASSIFICATION

The World Health Organization created the current standard of osteoporosis by which Medicare and other third-party payers reimburse for testing.² (Table 1). The standard was developed with data collected using dual energy x-ray absorptiometry (DEXA), but has been applied to quantitative computed tomography (QCT) and peripheral testing devices. The patient's BMD is summarized by a T-score, defined as the number of standard deviations from the mean BMD of a young, unaffected population. In 1998, the National Osteoporosis Foundation (NOF) issued recommendations, based on a cost-effectiveness analysis, to treat women with a T score less than -2.0 in the absence of additional risk factors, and women with a T score less than -1.5 who have additional risk factors.³

Absolute BMD varies from one site to another. The lowest T-score determines the patient's overall risk of fracture at any body site. Measurements that can be considered include the spine, femoral neck, forearm, or total body analysis by 1.) DEXA, 2.) the spine by QCT, or 3.) the heel or phalanx by peripheral devices. With hip measurements, there are actually two areas assessed. The "total femoral neck" includes the smaller area simply called the "femoral neck." The "total femoral neck" is the only measurement typically distributed to referring physicians on color DEXA printouts. A low measurement at any site is predictive of fracture risk at the site measured and any other site, but usually has the strongest predictive value at the site measured. For example, for every standard deviation decrease in the hip density, there is a 2.8-fold increase in the risk of a hip fracture, a 1.7-fold increase in the risk of a lumbar spine fracture, and a 1.8-fold increase in the risk of a distal radial fracture.^{4,5}

Abbreviations Used:

BMD	bone mineral density
DEXA	dual energy x-ray absorptiometry
fPYD	urine free pyridinoline
NHANES	National Health and Nutrition Examination Survey
NOF	National Osteoporosis Foundation
NTx	N-terminal telopeptide of type I collagen
QCT	quantitative computed tomography

CONFOUNDING FACTORS

DEXA is the best modality for determining the bone mineral density for the "average" person with no confounding factors, since measurements are typically performed at two sites, the spine and the hip. Additional imaging can be performed at the forearm and/or total body, depending on the clinical concerns and patient history. The disadvantage of DEXA is that it renders a two-dimensional representation of a three-dimensional process. The density measurement may be falsely elevated from an occult compression fracture, endplate sclerosis and facet hypertrophy, scoliosis, atherosclerotic disease, and ingested artifacts. Less commonly, apparent density can be lowered by a destructive lesion and prior laminectomy (Table 2). The BMD is not as accurately measured in those at the extreme limits of body weight because the soft tissue attenuation algorithms are optimized for people between 125 and 200 pounds. These confounding factors are eliminated by QCT, which studies a small three-dimensional region of interest.⁶

IS FRACTURE RISK DETERMINATION THAT EASY?

No. BMD is only one of a number of risk factors for fracture (Table 3).⁴ There are many 70-year-old, frankly osteoporotic women who do not have fractures. There are some 45-year-old perimenopausal, mildly osteopenic patients who do. All identifiable risk factors must be considered.^{7,8,9}

Risk factors are additive to the patient's overall risk. The presence of one or two risk factors increases hip fracture absolute risk by 1% over the patient's lifetime. The presence of 5 or more risk factors increases the hip fracture absolute risk by 10% over the patient's lifetime.¹⁰

The documentation of a prevalence fracture is also extremely important, and increases the fracture relative risk by 10-fold in those with a normal BMD, and by 25-fold in those with a low BMD.¹¹

CHANGE WHAT CAN BE CHANGED

Modifiable factors should be addressed. Patients should optimize their intake of calcium and vitamin D, and engage in moderate exercise of 40 minutes, three to five times per week. Hormone replacement therapy should be considered for all perimenopausal and postmenopausal women. Patients should refrain from excessive use of alcohol, caffeine, and tobacco. Fall prevention and eyesight correction should be discussed with elderly patients.³

USING DENSITOMETRY DATA TO FULL ADVANTAGE

The Z-score is another common value in densitometry reports. The Z-score is the number of standard deviations from the mean BMD of a reference population the same age as the patient. If this number is very low or very high and unexplained, a metabolic workup is usually recommended. Typically, when a patient has a Z-score less than -2.0, further evaluation for a secondary cause of osteoporosis is undertaken. Other patients requiring further evaluation include those with a normal BMD and an atraumatic fracture, those with renal stones and a low BMD, and those with a decreasing BMD despite pharmacological treatment for osteoporosis.⁶

DEXA and QCT provide images that may warrant additional investigation, such as a destructive bone lesion, fracture, or unsuspected liver or kidney lesion (in the case of QCT).

QCT usually can detect an occult fracture in the lumbar spine after a detailed analysis of the images, density comparisons of the four measured vertebral bodies, and use of a lateral scout "scanogram." The DEXA PA two-dimensional image may not define a mild compression fracture easily. However, a careful analysis of the density comparisons of the four measured vertebral bodies may prompt the densitometrist to recommend correlation with standard radiographs to determine if relative osteosclerosis is secondary to degenerative changes, an occult fracture, or an osteoblastic process (Table 2).

If the patient is suspected of having hyperparathyroidism, DEXA is the preferred modality, since it can demonstrate the preferential cortical bone loss in the ultradistal radius that is seen in this disorder.

COMPARING SEQUENTIAL EXAMS

It is preferred that patients be reevaluated at the same testing site. Each densitometry machine has its own precision error, which is determined by a precision experiment after six months of operation. Typically, this error is less than 2%, but is expressed as an absolute number for each machine and each body site. In order for the test to demonstrate response to pharmacological intervention, the bone

mineral density increase must surpass this precision error. If the patient transfers from one machine to another made by the same manufacturer, then the bone mineral density increase must surpass both precision errors (about 4%).

If the patient transfers from one machine to another made by another manufacturer, then the increase in BMD must surpass both precision errors plus an adjustment for the differences between the machine reference populations and edge detection methods. The industry has created a standard measurement, called the sBMD (expressed in mg/cc²). However, even with the adjustment, Lunar measurements tend to be slightly higher than Hologic measurements. Norland measurements tend to be slightly lower.

COMPARING MODALITIES

There is no consensus on comparing different densitometry modalities. Currently, the FDA-approved marketed devices include DEXA, QCT, and various peripheral devices that have shown accurate measuring capabilities. Each device operates on the basis of different physical principles. Therefore, even when a standard reference population (typically NHANES III) is employed, there will be differences in measurements and in the resulting T-scores. The variability in measurements is less for the young normal population and increases as the number of confounding factors increases.

QCT has been criticized for "overdiagnosing" osteoporosis because it does not take confounding factors into account. But QCT may be a better technique than others, because it produces more reproducible results in patients with confounding factors and is slightly more sensitive at detecting changes in bone mineral density than DEXA.

If a patient is determined to be osteoporotic or osteopenic using a peripheral device, then a central densitometry test is necessary as a baseline. Changes may be detected at one year in the spine, but not for 3 years in the hip and for even longer at peripheral sites.¹¹

Ten percent of patients with a normal peripheral BMD result will have an abnormal axial measurement. If the patient is determined to have significant risk factors, then reevaluation by a more central device may be indicated. In fact, one can argue that patients with significant risk factors for osteoporosis probably warrant central testing initially.¹²

RETESTING

Some patients may not require any testing, including those patients who would not consider treatment.

Regardless of BMD, retesting is indicated annually for:

- * Patients on pharmacological intervention or high dose steroid therapy (≥ 5 mg prednisone/day X 3 months),
- * Patients with organ transplants,
- * Patients with high bone turnover by urinary markers such as cross-linked N-terminal telopeptide of type I collagen (NTx) or urine free pyridinoline (fPYD).

Most other patients are reevaluated in two years.^{7,13} (Table 4)

LIMITATIONS OF BMD TESTING: ESSENTIAL POINTS REVISITED

Low bone mass does not mean bone loss.

Typically, females at age 23 and males at age 40 have achieved maximal BMD. However, a particular patient may not have achieved the average maximal BMD for a person of his or her sex.

Low bone mass does not distinguish primary causes of bone loss from secondary causes of bone loss.

Therefore, if a patient with bone loss does not have a clinical history or risk factors consistent with primary osteoporosis, then a metabolic workup should be employed. As stated earlier, a Z-score less than -2.0, loss of BMD on treatment, low BMD with renal stones, and normal BMD with atraumatic fractures should all prompt a metabolic workup for alternate causes.

Artifacts may interfere with results.

The final T-score may not be representative for the patient because of the confounding factors listed in the report and summarized in Table 2.

BMD does not predict the rate of bone loss.

Typically, the greatest rate of bone mineral loss for women occurs during the first eight years following menopause. There may be a resurgence of accelerated bone loss once again at 70-80 years. Males tend to lose BMD at a higher rate after the age of 65, although the rate of loss is not as high as in females. The rate of bone loss can be

Table 1. World Health Organization bone mineral density criteria for osteoporosis

Classification	T-Score
Normal	> -1.0 SD
Osteopenia	< -1.0 SD & > -2.5 SD
Osteoporosis	< -2.5 SD
Severe Osteoporosis	< -2.5 SD with fragility fractures

Table 2. Factors that increase or decrease apparent bone mineral density (BMD) on DEXA

Increased BMD	Decreased BMD	Risk Factor	RR
Scoliosis	Prior laminectomy	Maternal history of hip fractures	2.0
Osteoblastic lesion	Osteolytic lesion	Height	1.2
Occult fracture		Previous hyperthyroidism	1.8
Atherosclerotic disease		Benzodiazepines	1.6
End plate sclerosis		Anticonvulsants	2.8
Facet arthropathy		Inability to rise from chair	2.1
Posterior fusion rods		Poor depth perception	1.5
Pedicle screws		Poor contrast vision	1.2
Oral contrast agents		Low bone density (each 1 SD decrease)	1.6
Ingested calcium		Increase in weight (20%)	0.6
Ingested antacids		Walking for exercise	0.7
Nuclear-radiopharmaceuticals			
Pancreatic calcifications			
Mesenteric node calcifications			

Table 4. Reference sheet for patient densitometric reevaluation

None

Patients over 70 years old with multiple risk factors have sufficiently high risk that treatment is warranted without BMD testing. A baseline study is useful in monitoring response to therapy, if desired.

6-12 Months

Patients on high-dose steroid therapy (7.5+ mg prednisone / day for 3+ months), regardless of BMD

Yearly

1. Patients receiving FDA-approved osteoporosis drug therapy, to monitor response to therapy
2. Patients who have undergone organ transplantation
3. Patients who have evidence of high bone turnover by urinary markers, regardless of BMD

Every Other Year

1. Men and women ages 65+
2. All menopausal or estrogen deficient women before age 65.
3. Primary hyperparathyroidism.
4. Patients with BMD T-scores below -1.5, if major risk factors are present and no drug therapy is used.

determined by reassessing the BMD in one to two years by densitometry or by obtaining urinary markers of bone loss. The charge for one additional densitometry test is comparable to the charge for one sample of one urinary marker (such as NTx).¹⁴

BMD does not address other risk factors for fracture.

Low BMD is only one of a number of risk factors for fracture. With elderly patients, correcting eyesight and preventing falls are important subjects of ongoing patient counseling.

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BOOK REVIEWS

The Doctors Book of Home Remedies II,
Sid Kirchheimer and the Editors of Prevention Magazine
Health Books
Rodale Press, Emmaus PA, 1993

Patients often pore over lay self-help books. *The Doctors Book of Home Remedies II* follows on the best-selling heels of its predecessor. This book compiles advice from many medical sources about common conditions and complaints. It is written for the consumer in an accessible folksy style, and details advice about things that really bother people — things like belching and body odor, chapped lips and flu. It is peppered throughout with useful sections about when to see a doctor, so the intelligent reader finds a number of simple, common-sense remedies that he or she can try at home, coupled with information about when to seek more expert opinion.

That's the good news. The bad news is that the title is disingenuous, there is no methodology explained and very little evidence cited to support the advice. The author is not a physician, and the contents appear to have been assembled by the author and editors from interviews with some 500 "experts," many of whom are not physicians. It is not clear how the author chose his experts, nor is it made clear what qualifies an expert as an expert (though each expert has an academic title cited.) These experts have a huge specialty bias, something like 50 specialists to 3 primary care doctors in a sample of about 30 pages, which means some of the advice is spurious (like the suggestion that meditation will

prevent influenza) and some advice is simply missing (like what to do for nocturia).

In addition, there is very little evidence quoted in each section, so the strength of the advice can't be judged. The advice for forgetfulness includes exercise, watching TV talk shows(!), writing information down, thinking in rhymes, taking beta-carotene, taking the time to observe rather than see, and playing cards and board games. There is nothing here to tell the reader which to do first, or which is more likely to be effective.

Finally, *The Doctors Book of Home Remedies II*, though recently re-released, is copyright 1993, so some of its advice, like that to use peroxide for cerumen, is simply out of date.

On the other hand, *The Doctors Book of Home Remedies II* is just advice about mostly self-limited conditions. Little of this advice is likely to hurt anyone, so as a book, *The Doctors Book of Home Remedies II* is not harmful, but not overwhelmingly likely to be helpful either.

— Reviewed by Michael Fine, MD

Michael Fine, MD, a family physician, is President, Rhode Island Academy of Family Practice, and President, Center for Occupational and Environmental Health of Rhode Island.





Vital Statistics

Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Underlying Cause of Death	Reporting Period			
	April 1999	12 Months Ending with April 1999		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	226	3,028	306.3	3,518.0
Malignant Neoplasms	176	2,466	249.5	6,513.5**
Cerebrovascular Diseases	49	569	57.6	761.0
Injuries (Accident/Suicide/Homicide)	38	383	38.7	7,439.5
COPD	44	479	48.5	452.5

Vital Events	Reporting Period		
	October 1999	12 Months Ending with October 1999	
	Number	Number	Rates
Live Births	1,137	13,404	13.5*
Deaths	771	9,844	10.0*
Infant Deaths	(6)	(93)	6.9#
Neonatal deaths	(6)	(70)	5.2#
Marriages	993	7,735	7.8*
Divorces	219	2,838	2.9*
Induced Terminations	446	4,928	367.7#
Spontaneous Fetal Deaths	191	1,149	85.6#
Under 20 weeks gestation	(184)	(1,075)	80.2#
20+ weeks gestation	(7)	(73)	5.4#

**Excludes one death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 988,480

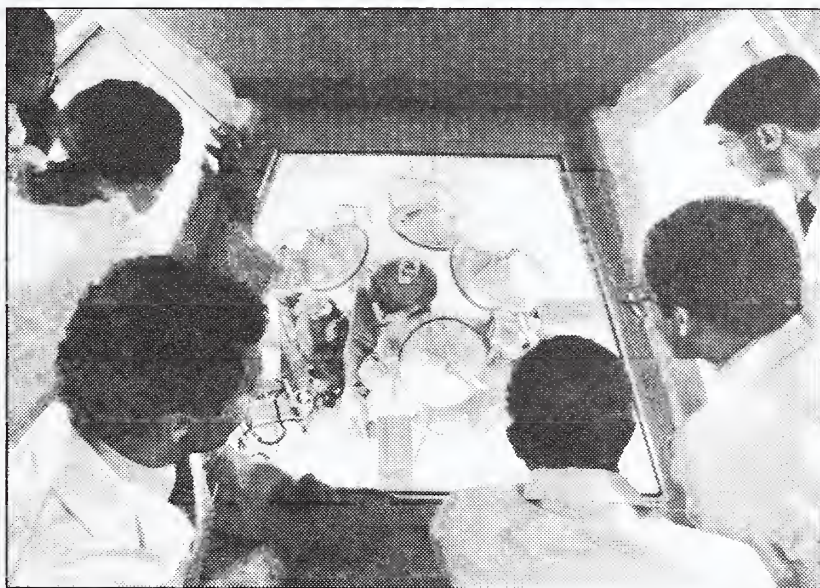
(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population

Rates per 1,000 live births

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NINETY YEARS AGO

✿ [APRIL, 1910] ✿

Frank E. Peckham, MD, in "Fractures of the Lower End of the Radius," urged lateral and anteroposterior x-rays. He delineated "perfect" from "satisfactory" outcomes: "A perfect result can only mean one thing. No deformity and just the same mobility of the wrist in all directions as the other or normal wrist...everything must be just as good as it was before the injury." With satisfactory results, "there seems to be a difference of opinion on the part of the attending surgeon and the patient."

S.S. Burton, MD, in "Child Life," pleaded the case of children abused by horrific schools, parents, and communities. "I have long been impressed with the fact that the child at school, on the street, and I am sorry to say, often times at home, is seldom understood." Specifically, Dr. Burton spoke against corporal punishment ("very seldom necessary"), long school days ("Five hours a day is too long a period to sit quietly and be attentive"), the placement of blackboards (leads to eye strain), inadequate meals ("Few mothers know how to feed their children"), mercenary parents ("I have found [children] asleep in the doorways and in the depot after 11:00 at night, not daring to go home till all their [news]papers were sold...If [children] lost money, parents would punish them.")

Charles Peckham, MD, in "Chronic Constipation," advised, "...it might be as well if we placed our bottles of cathartic tablets upon the same shelf with other dangerous drugs and dispensed them with the same caution."

The minutes of the Meeting of the Providence Medical Association included discussion of the library's purchase of foreign journals. To one member's suggestion that the usage did not warrant the expense, another countered, "We shouldn't eliminate the foreign journals because few members read them. Others will need them in the future."

FIFTY YEARS AGO

✿ [APRIL, 1950] ✿

Clifton B. Leech, MD, tabulated the number of patients with cardiovascular syphilis seen at the Rhode Island Hospital syphilis clinic since January 1934, the clinic's opening: 119 of 1329 patients. In the last few years the clinic staff had seen a decrease in the effects of late syphilis, though Dr. Leech conceded that the War made it hard to discern trends. Overall, he estimated that 10,000 Rhode Islanders had or have syphilis.

Nicholas Migliaccio, DMD, in a guest editorial ("Sodium Fluoride in Dental Decay") argued for fluoridated water: "The

DMF (Decayed-Missing-Filled) rate is about 60% lower in children 12 to 14 years of age than it is in the same group in communities having no fluorine in the water supply." Grand Rapids, Michigan, was the first community in the United States to add fluorine to the water; eight other communities in the United States and Canada followed suit. The effectiveness of fluorine in gum, mouthwash, tablets, and dentrifices was not yet proven. Congress just created a National Institute of Dental Research, under the NIH.

TWENTY FIVE YEARS AGO

✿ [APRIL, 1975] ✿

In "Treatment of End Stage Renal Disease in Rhode Island: A Status Report," Serafino Garell, MD, FACP, Joseph A. Chazan, MD, FACP, and Sewell I. Kahn, MD, cited the surge of patients since the advent of chronic hemodialysis in 1960. In Rhode Island, the procedure was instituted first at the Veterans Administration Hospital in 1971 (previously, Rhode Islanders had gone to Boston for dialysis). The Rhode Island Hospital Dialysis Unit and the unit at Miriam followed months afterward. In 1973 a satellite unit (to RIH) opened. As of 1975 the state had 42 beds, with 107 patients, at an annual average cost of \$23,400 each. The authors predicted a continuing increase in this census.

In "A Case of Hematuria," Tobias M. Goodman, MD, described a 43 year-old man, with no other symptoms and with normal physical exam, Pap smear, and laboratory tests. A right nephroretectomy showed a grade III cell carcinoma of the right renal pelvis. Dr. Goodman concluded, "More than 20% of patients [with hematuria] will have cancer somewhere in the genitourinary tract."

The eight-member Ad Hoc Committee of the Rhode Island Medical Society on Psycho-Active Medications in Children (chaired by John E. Farley, Jr., MD) advised, "Psychostimulant medication has a definite place in the management of children with attentional control problems."

A subcommittee of the Rhode Island Health Science Education Council (chaired by Robert M. Lewis, MD) presented "A Survey of Physicians in Rhode Island and An Evaluation of Needs." They projected that RI would need 257 more PCPs and 127 specialists (anesthesiology, dermatology, neurology, obstetrics/gynecology, ophthalmology, otolaryngology, physical medicine, psychiatry, radiology, urology - "the other specialties are in ample or possibly excess supply.") The subcommittee calculated that the state had 1167 licensed physicians under age 65, in active practice. (Thirty percent of active physicians were older than 65.)



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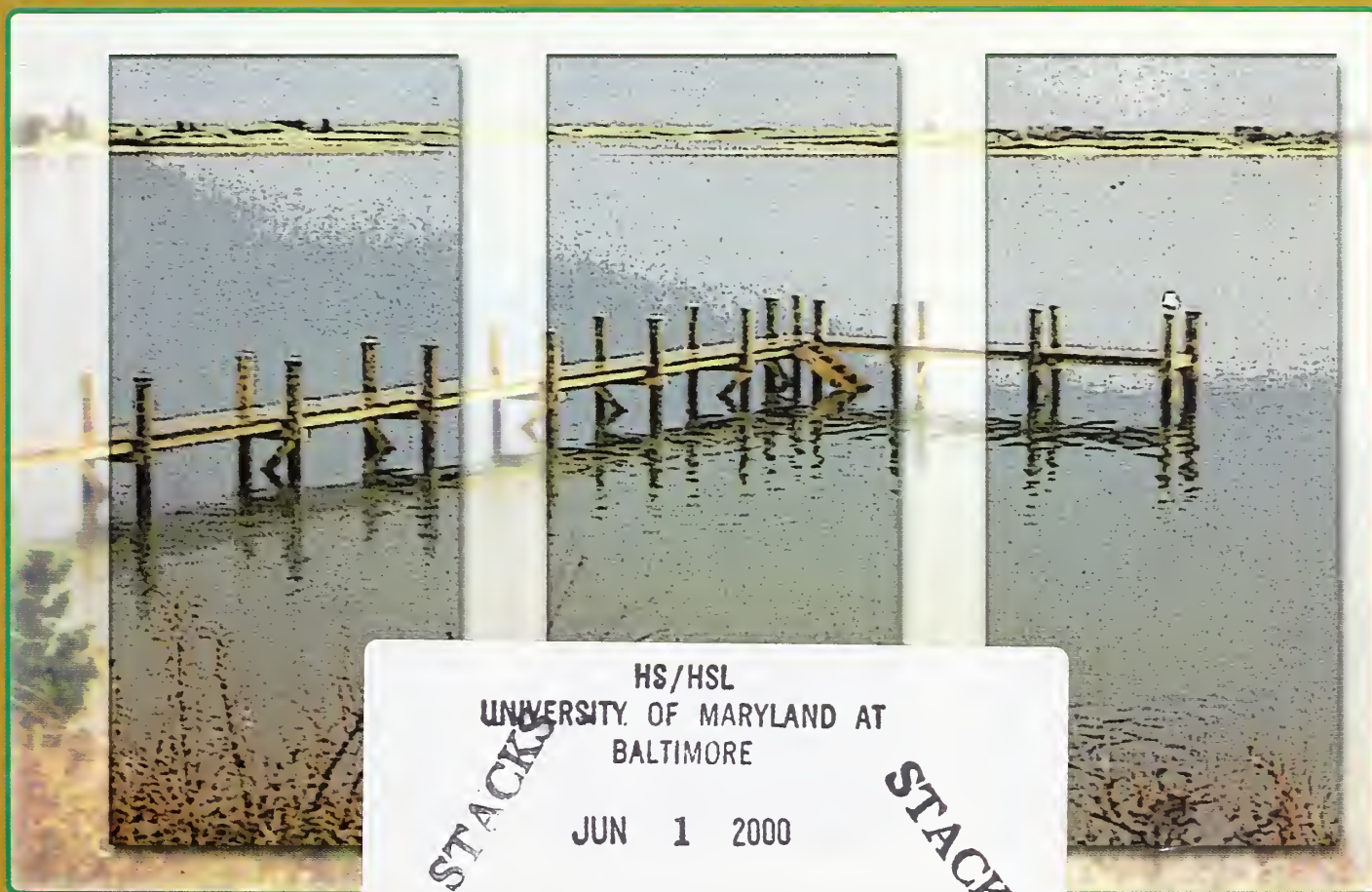
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COMMENTARIES

“There Is No Constitutional Right to Health Care”

David Stockman, President Ronald Reagan's director of the Office of Management and Budget, said that. He was also that administration's spokesman for defending the quality of federally-sponsored school lunches who observed that these lunches were more nutritious than their critics claimed since ketchup really was a vegetable. However, he was correct on the health care issue. Health care is not guaranteed in the Constitution. And, of course, it's frequently not available. More and more, even middle class Americans have been learning what it's like to be uninsured and to have to make significant sacrifices to buy medication or to see approved providers even when insured. Most of us who use the health care system, doctors included, are finding more and more wrong with it.

Health care is an unusual service industry. It is partly regulated but free enter-

prise is encouraged. Wall Street bets on it. In the inpatient sphere large corporations have evolved that own hospitals. Since much of the cost for admissions is fixed, the profits must be squeezed out via efficiency or decreased services. As Woolhandler and Himmelstein have shown, this profit is achieved through diminished services, not via efficiency. Administrative costs actually rise in the private hospitals, as they do in for-profit HMOs. And, while HMOs are going out of business there still seems to be a brisk market for private corporations which buy private medical practices.

I am reminded of amazon.com: the more the company loses, the more the stock owners make. There is a perverse logic that may make sense in some looking glass world.

It seems, to this naïve observer, that medical care should be a right in our wealthy, developed country, as it is in west-

ern and eastern Europe, and that the free enterprise system is not any more suitable for modern medical care than it is for fire and police services. A century or so ago fire departments were private companies. One paid in advance for service. If your house was on fire and you hadn't purchased a fire department service, your house burned down. This turned out to be a less efficient use of the service than making it universal. Yet there is no Constitutional right to police or fire protection. It somehow became ingrained as a mandatory function of civil government, but it wasn't always. There are obvious differences between these services and medicine but the main one is money. Yet every single commentator agrees that health care would be less expensive per person if expanded so that illnesses would be treated early, before complications set in and costs ran up. An ounce of prevention, as they say, is worth a pound of cure. The indirect benefits, both social and economic would be enormous.

As our health care financial “system” slowly grinds to a halt, I can only hope that we will one day look back at this time in wonder, since universal medical care will then be considered as much a “right” as police and fire protection.

— Joseph H. Friedman, MD

A Terrible Tragedy in the Irish Sea

When Queen Elizabeth declared to the Spanish ambassador that the ocean waters and the air were free to all, her sole concern was the unhindered passage of her English sailing ships on the high seas. The reference to air was but metaphoric license. And yet, even in the Elizabethan era, well before the industrial revolution, England was encountering grave problems in providing its subjects with unhindered access to fresh air.

In the English navy at the dawn of the 17th Century, many seamen fell ill when confined, for any length of time, to the lower holds of the sailing vessels. And, as ship-building advances allowed for larger ships, the problem grew more severe. The technical question arose: How could fresh air be conveyed to the lower decks without compromising the structural integrity of the ship's hull or its sailing capability? Lengthy canvas tubes which directed the prevailing winds to the lower decks were adopted, but rarely did they afford much relief. And when the ship was becalmed or encountered rain storms, these windsails became inoperative.

A more fundamental question was then asked: Why were sailors sickened by the stale, malodorous air of the lower decks? Certainly lingering odors permeated most 17th Century homes and public places, yet it was largely in the holds of ships that problems akin to suffocation arose. In the absence of information concerning the composition of air, it was presumed that an unidentified poison [possibly from putrefying sources] was tainting the atmosphere. Air was clearly es-

sential for life; but why it was essential remained a mystery until the 18th Century when a succession of discoveries by Priestley, Lavoisier and others revealed air to be a mixture of gases; and one of these, now called oxygen, was critical for survival.

By the 18th Century the problem of inadequate ventilation widened as mines were deepened, tunnels made longer and ships, prisons, orphan asylums and hospitals made larger.

Christopher Wren, England's great architect, was asked to do something about the wretchedly oppressive air in the Houses of Parliament. Wren introduced egress chimneys and had thousands of holes bored in the floor to encourage a passive flow of air through the chambers. Wren, a prudent soul, refrained from mentioning that legislative chambers, by virtue of the activities that they fostered, needed extra ventilation.

One of the first to seek a solution to the problem of stale air was Stephen Hales, an 18th Century Cambridge-trained Anglican cleric. His pastoral responsibilities were light and for six decades he devoted most of his energies to scientific inquiry. Hales' principal interest lay in the dynamics of the cardiovascular system, specifically the nature of blood pressure. He approached the problem of shipboard ventilation by presuming that passive transfer of air was inadequate in larger ships, and that an active mechanism was needed. He then devised large air-pumps based on the principle of church organ bellows. His mechanism worked, but only when the pumps were manned by fresh crews of workers.

A ferry regularly plied the Irish Sea between the ports of eastern

Ireland and Liverpool. Late in 1847, 73 passengers in steerage died of suffocation during the relatively short voyage. This terrible tragedy prompted an official inquiry into ventilation of sequestered spaces. A noted British physician, Dr. N. Arnott, prepared the report, submitted in December, 1848. This document was written at a time when the germ theory of disease had not as yet been accepted. Arnott stated: "Epidemic diseases . . . have been caused only because aerial poisons were allowed to lurk and accumulate in ill-ventilated places." Accordingly, he designed mechanical pumps to force fresh air into the lower holds. His reasoning might have been wrong but his results were good. Arnott's design had two material advances over the pumps designed by Hales: First, they used steam-engines as motive force; and second, the intake valves were now constructed of durable rubber. When Arnott's contrivance was put to use on a prison ship carrying 500 convicts to Australia, only one death was recorded during the long voyage. Arnott, in passing, made reference to the many immigrants who had perished, allegedly from ship-fever, in the steerage holds of the great ships going to America; and he speculated that many lives might have been saved had forced ventilation been introduced.

But the advent of steam engine propulsion on ships brought still further medical problems to those required to exist in the lower holds of ships. Stokers who worked the great furnaces became readily dehydrated, many going into shock. And those that withstood the heat

were gradually incapacitated by kidney and bladder stones, the consequence of chronic dehydration.

A spate of royal commissions finally created guidelines for maritime ventilation. Minimum requirements were also determined for various land-based facilities. For example, an asylum for orphans must allot each inmate a minimum of 1,000 cubic feet of fresh air per hour; for convicts, 1,500 cubic feet; for adults in hospitals, 2,500 cubic feet; and for stabled horses, 12,000 cubic feet. Hospitals, sanatoria and asylums were redesigned with finger-like pavilions rather than large central buildings thus maximizing the window area. Internal ducts with exhaust fans were installed to extract hot air from facilities such as furnace rooms and kitchens.

Poor prison ventilation prompted a variety of novel mechanical solutions. At London's Newgate Prison, a rooftop windmill was employed to hasten the exchange of air. Motor-driven fans improved the situation in still other sites. But a prison remains a prison; and it would require more than air-moving equipment to cleanse it of its corrupt atmosphere. In 1895 Oscar Wilde was imprisoned for two years for crimes which the coy British called his moral obliquity. In his *Ballad of Reading Gaol*, he describes the fetid, confining atmosphere of his cell as follows: "The vilest deeds, like poison weeds, bloom well in prison air."

— Stanley M. Aronson, MD

The Rhode Island Department of Health

The Rhode Island Department of Health (HEALTH) is a relatively small state department. Our budget of \$74 million represents about 2% of total state expenditures. Our workforce of 460 employees is only 3% of the state workforce. And yet HEALTH has broad responsibilities. We must meet high expectations for the health of Rhode Islanders.

Section 23-1-1 of the General Laws of Rhode Island defines our mission: "The Department of Health shall take cognizance of the interests of life and health among the peoples of the state; shall make investigations into the causes of disease, the prevalence of epidemics among the people, the sources of mortality, the effect of localities, employments and all other conditions and circumstances on the public health, and do all in its power to ascertain the causes and the best means for the prevention and control of diseases or conditions detrimental to the public health, and adopt proper and expedient measures to prevent and control such diseases and conditions in the state." In a nutshell, HEALTH is asked to carry out epidemiological analyses and interventions aimed at the prevention of disease and the promotion of health.

HEALTH has seven operating divisions: Central Management, Disease Prevention & Control, Family Health, Environmental Health, Health Services Regulation, the Laboratory, and the Medical Examiners Office. Within these operating divisions, there are a total of 23 separate offices and more than twice as many programs. Because we are a mile-wide and an inch-deep, we must meet our mandate through effective collaboration.

HEALTH touches almost every aspect of our daily lives: food, water, air, housing, highway safety, schools, worksites, the mass media, and of course health care services. In fact, HEALTH regulates virtually every health profession, every health care facility, and every managed health care plan. In one way or another, HEALTH is involved in every aspect of the health care system.

Abbreviations Used:

HEALTH	Rhode Island Department of Health
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In Rhode Island there are no county or city health departments. In 1964, the Rhode Island General Assembly consolidated all local and state public health functions into one statewide Department of Health in order to improve the efficiency and effectiveness of public health practice in Rhode Island, the smallest state in the union.

The advent of the Internet is revolutionizing the practice of public health. Now, the public can truly have access to public health information. Now, HEALTH truly has the opportunity to communicate critical public health messages to the general public and the professional community. Please take the time to visit our website (<http://www.health.state.ri.us>) and learn more about us. And please let us hear from you. How are we doing?

— Patricia A. Nolan, MD, MPH

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The Office of Primary Care at the Rhode Island Department of Health

John Lopez, MBA, Mary Anne Miller, RN, MPH, Maureen Ross, RDH

BACKGROUND

In the not too distant past, health care access for our poorest and most vulnerable populations was almost nonexistent. Hospital emergency rooms afforded some relief from acute problems but few opportunities for prevention of disease and health promotion. Reliance on hospital emergency departments as a source of routine care is often cited as an indicator of poor access to primary health care.¹

In the mid-sixties, Drs. Jack Geiger and Count Gibson received a grant from the federal Office of Economic Opportunity to establish two neighborhood health centers, one in Massachusetts and the other in Mississippi. The vision nurtured by these physicians led to the development and expansion of non-profit community health centers (CHCs) nationally. Currently, a network of CHCs throughout the nation serves more than 10 million people, a significant portion of whom are uninsured and poor. In Rhode Island, 13 CHCs provide primary health care services to 70,000 patients, many of whom would not have health care access without this essential network of providers.

The Office of Primary Care at the Rhode Island Department of Health (HEALTH) receives operational funding through a Cooperative Agreement from the federal Bureau of Primary Health Care (BPHC), one of four Bureaus within the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services. BPHC's vision is "to achieve 100% access to health care and zero disparities in health status by 2010." Its mission is to increase access to comprehensive primary and preventive health care and to improve the health status of underserved and vulnerable populations.² As part of its

commitment to communities that emphasize ongoing federal and state collaboration, the BPHC supports a PCO (Primary Care Office) and a PCA (Primary Care Association) in each state. HEALTH's Office of Primary Care is the PCO in Rhode Island; the Rhode Island Health Center Association, representing CHCs statewide, is the PCA.

A Memorandum of Agreement (MOA) between the PCO and the PCA establishes the infrastructure for quality, community-responsive primary care.

Other BPHC-supported programs (like the Travelers Aid Society, Rhode Island's largest program for the homeless) are included as partners in the MOA. Representing BPHC, the Region I Field Office in Boston works individually and collectively with the New England region.

THE OFFICE OF PRIMARY CARE MISSION & KEY PARTNERSHIPS

The Office is responsible for evaluating primary care capacity, assessing the supply and distribution of primary care providers, and promoting access to primary care, particularly for at-risk populations throughout the state. In addition, the Office provides technical assistance to and links with a wide variety of other HEALTH programs that seek to enhance primary care access. The Office works not only with the well-established network of CHCs but also has liaisons with other providers that comprise the state's primary care "safety net;" e.g., community hospitals and outpatient clinics. To improve access, particularly for vulnerable, underserved populations, it is essential also to have firm linkages with academic health professions training programs and professional organizations throughout the state and north-

Abbreviations Used:

ACI	Adult Correctional Institute
BPHC	Bureau of Primary Health Care
CHC	community health center
HEALTH	RI Department of Health
HPSA	Health Professional Shortage Area
HRSA	Health Resources and Services Administration
MOA	Memorandum of Agreement
NHSC	National Health Service Corp
PCA	Primary Care Association
PCO	Primary Care Office
PCPAC	Primary Care Physician Advisory Committee

east region. Working with these organizations is key to helping Rhode Island's primary care environment be more responsive to the needs of our citizens.

RHODE ISLAND'S PRIMARY CARE INFRASTRUCTURE

There are a variety of access points for entry into the primary care delivery system; e.g., CHCs, hospital outpatient clinics and emergency rooms, and private physician practices. However, several features distinguish CHCs from other providers of primary care. As a core function, CHCs work to provide access to primary care for low-income, uninsured and underserved populations. Also, as a condition of federal support, CHCs must serve populations located in federally designated underserved areas and each CHC governing board must be comprised of a majority of healthcare consumers from the community. CHCs do not provide health care services free of charge. However, for those without insurance, a sliding fee schedule based on ability to pay results in some patients receiving services for free while others are assessed a minimal fee. Obtaining medication for patients with limited resources presents a challenge

for safety net providers. The CHCs and Travelers Aid provide some medications for their uninsured patients, and the University of Rhode Island's College of Pharmacy referral program (*Medication for the Needy*) helps residents to obtain certain medications.

According to HEALTH's Office of Medical Licensure & Discipline, there are about 3,300 physicians currently licensed to practice in the state: 1,350 describe their "primary specialty" as one of the following: doctors of medicine and osteopathy: general or family practice; general internal medicine; general pediatrics; or obstetrics and gynecology.³ Using the federal definition, the number of primary care providers in Rhode Island includes: 1) general internal medicine - 634 practitioners (47%); 2) general pediatrics - 281 practitioners (21%); 3) family practice - 254 practitioners (19%); and obstetrics/gynecology - 181 practitioners (13%).

UNINSURED & VULNERABLE POPULATIONS

Health Care Coverage & Routine Physician Visits

Health care coverage is a major determinant of access. Persons without coverage are less likely to have a usual source of health care, more likely to have an unmet health care need, and less likely to receive preventive health care services. (Figure 1: RI Adults With No Health Care Coverage) (Figure 2:

The Office is responsible for evaluating primary care capacity, assessing the supply and distribution of primary care providers, and promoting access to primary care, particularly for at-risk populations throughout the state.



Source of Health Care Coverage By Race/Ethnicity)

The percentage of uninsured adults in Rhode Island has remained relatively stable over the past seven years. However, the number of adults whose coverage is provided privately (employer or self-paid) has decreased, and those whose coverage is provided through government programs (e.g., RIte Care, Medicare) has increased.⁴

Other key health status indicators include:

- RI population segments with highest proportions that lack health care coverage: 20% of adults ages 18-24; 21% of all adult Blacks; 22% of all adult Hispanics; 18% of adults with less than high school education.⁵

- Ten percent (22,000) of Rhode Island children are uninsured. Of this group, 77% live in families under 250% of the federal poverty level and are therefore eligible to enroll in RIte Care.⁶
- Males in Rhode Island were somewhat more likely to be uninsured than females. However, males were more likely to be covered by employer-paid plans and females by public programs.⁷
- During the period 1990 - 1996, the percentage of Rhode Islanders who had a routine physician visit (within the past 12 months) increased from 61% to 71% although the mean number of physician visits remained constant over this period (3.7 visits for 1990 and 3.8 visits for 1996).⁸
- Having health care coverage is associated with one or more visits as well as with routine visits. In 1996, 89% of those with health care coverage reported one or more visits, compared to 66.5% of those without coverage. Likewise, 73.4% of the insured reported a routine visit, compared to 49.2% of those who were uninsured.⁹
- The key primary care objective outlined in the national *Healthy People 2000*, *Healthy People 2010* Draft for Public Comment, and in *Rhode Island Healthy People 2000*, remains unchanged. It is to "Increase to at least 95% the proportion of people who have a specific source of ongoing primary care." The national baseline was 80% in 1991, and 84% in 1994. The Rhode Island baseline was 89% in 1990, and 91% in 1996.¹⁰

COMMUNITY HEALTH CENTERS & THEIR PATIENTS

Rhode Island's 13 CHCs provide care to about 70,000 unduplicated users and log about 232,000 encounters annually. Most patients (83.5%) are poor or near poor (< 200% of the federal poverty level -FPL). In terms of health care coverage, 31% are unin-

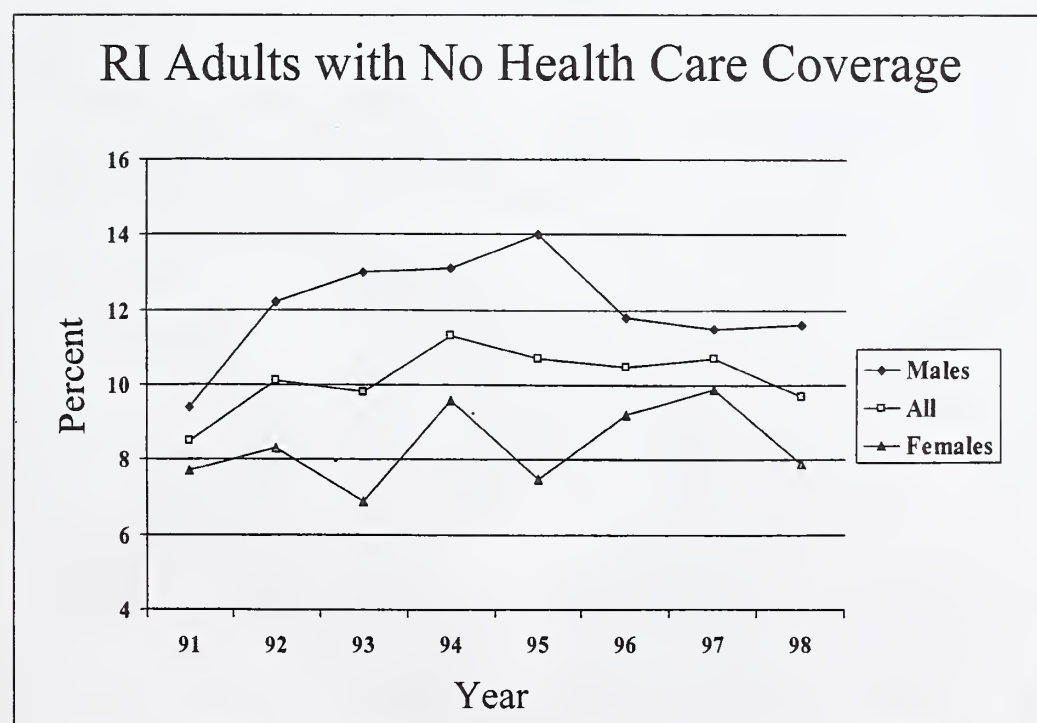


Figure 1.

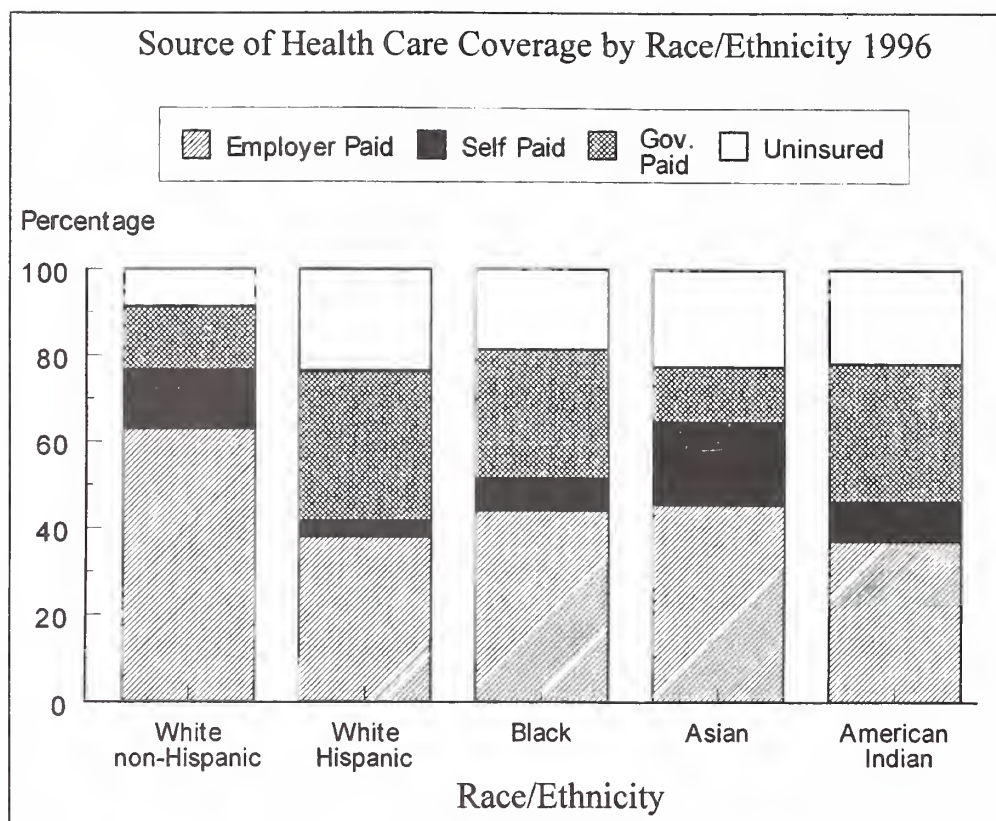


Figure 2.

sured, 33% RIte Care, 8% Medicaid, 7% Medicare, 21% private insurance.¹¹ Another BPHC-supported program in Rhode Island, the Travelers Aid Society, serves 2,398 primary care patients, of whom 88% are uninsured.¹²

OPC CORE FUNCTIONS

Assessment of Primary Care Capacity/Health Professional Shortage Area Designations

A major initiative of the Office is the preparation, analysis, and submission of Health Professional Shortage Area (HPSA) designation applications. A HPSA designation (from the BPHC) identifies areas with an inadequate supply of primary care providers. A variety of state and federal programs require a HPSA designation as part of funding criteria (e.g., National Health Service Corp Scholarship and Loan Repayment Programs, State Loan Repayment Programs, Medicare Incentive Payments Program).

The HPSA system has three designations that focus on whether an area has a shortage of primary care physicians, dentists, or mental health professionals available to serve people in a specific rational service area. A HPSA can be defined by a distinct geographic area (such as a city), a specific popula-

tion group within the area (such as the poor, those below 200% of the federal poverty level), or a specific public or non-profit facility (such as a correctional facility). The Office identifies populations and geographic areas throughout Rhode Island that, according to federal regulations, have an inadequate supply of clinicians for the population within the rational service area. The Office then develops an application with detailed information and statistics about populations or areas in the state that meet designation guidelines. Typically, the Office submits 6-8 HPSA applications annually. Primary care HPSAs (either current or with a renewal application pending) include specific areas within Providence, Woonsocket, Central Falls, Pawtucket, Newport County, Burrillville, Foster, Glocester, Narragansett Indian Tribe, and three public/non-profit facilities: the Department of Corrections' Adult Correctional Institute (ACI), Wood River Health Services, and Health Center of South County.

Recruitment & Retention of Primary Care Providers

Another core function of the Office is to support efforts to recruit and

retain health care professionals dedicated to serving communities lacking adequate access to primary care. The Office is involved in the administration of four National Health Service Corp (NHSC) programs: 1) the Scholarship Program; 2) Federal Loan Repayment Program; 3) State Loan Repayment Program; and 4) the Student Experiences and Rotations in Community Health (SEARCH) Program.

NHSC Scholarships offer monthly stipends and payment of tuition and expenses for up to four years of health professions education. For each year of support, scholars must serve one year in a HPSA upon completion of training. The NHSC Federal & State Loan Repayment Programs provide fully trained clinicians with repayment of qualified educational loans if they serve in a HPSA, in addition to a competitive salary. Finally, the NHSC SEARCH Program matches health professions students with clinical mentors/preceptors who work in underserved communities. Participants receive a \$2,000 stipend upon completion of the eight-week community health rotation that includes visits to community-based health and social service agencies, a didactic component, and a final site-specific project that benefits the community. About 20 students from a variety of disciplines including medicine, dentistry, advanced practice nursing, physician assistant, and social/behavioral/mental health participate annually in the RI SEARCH Program.

Every year, about 15 primary care professionals in Rhode Island are selected to participate in the NHSC Scholarship Program and the State & Federal Loan Repayment Programs.



Participation in RI Loan Repayment and Scholarship Programs is as follows: 53% physicians, 27% dentists, 13% nurse practitioners, 3% certified nurse midwives, and 2% dental hygienists. The Office works closely with training programs in RI and throughout the northeast region to develop strong academic linkages for the mutual benefit of students, training programs and underserved communities statewide.

PRIMARY CARE PHYSICIAN ADVISORY COMMITTEE (PCPAC)

Established in 1992, the Primary Care Physician Advisory Committee (PCPAC) has advised HEALTH and the Office on programmatic and policy issues. The PCPAC consists of 16 primary care physicians representing each of the primary care academies, the medical society, and hospital and community-based practitioners. It meets monthly with staff support provided by the Office.

Meetings typically focus on one topic, with stakeholders invited to participate. Recent topics include the hospitalist concept, standardized forms and policies for school health requirements, children's mental health services access, physician-to-physician conflict resolution, improving access to specialty clinics for RIte Care members, and emergency room prior-authorization requirements. Since many of these issues involve a broad range of stakeholders, PCPAC is instrumental in the promotion of collaborative problem solving. Throughout the years, PCPAC has brought hospitals, community-based providers, insurance companies, and HEALTH and its sister state agencies, to the proverbial table. The Committee has proven to be one of the most efficient and effective means to promote inter-organiza-

tional collaboration focused on improving primary care in Rhode Island.

CONCLUSION

Providing universal access to comprehensive primary care remains critical to improving health status. The social cleavages of race, ethnicity, and income are mirrored in disparities in health status: vulnerable populations have higher rates of a multitude of diseases. Increasing access to primary care, particularly for the underserved, demands targeting resources and partnerships with primary care providers and community-based organizations. The Office of Primary Care functions as a change agent to facilitate improved access for vulnerable populations.

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Assessing and Responding to Pre/Periconception Risks – Early Experience with the Rhode Island Women's Health Screening & Referral Program

William H. Hollinshead, MD, MPH, Marguerite B. Vigliani, MD, Nancy E. Walsh, RN, MEd, Cheryl A. LeClair, MSW, and Lori A. Zelano

Approximately 250,000 women of childbearing age (ages 15-44) live in Rhode Island, about one-fourth of the state's total population. Each year, approximately 13,500 babies are born in Rhode Island and about 5,500 miscarriages and terminations are reported. It is estimated that between one-third and one-half of all pregnancies in Rhode Island are unintended.

Rhode Island has adopted the reduction of unintended pregnancies as a critical public health objective, and one of the draft national *Healthy People 2010* objectives focuses on increasing the proportion of pregnancies that are planned in the United States to at least 70%. A 1995 study estimated that about half of the women in a Rhode Island urban health center setting with a negative pregnancy test will return with a positive pregnancy test within a year. Many of these pregnancies are unintended, and many of these women are threatened by preventable risks to their own health and their baby's.

The Rhode Island Department of Health's Women's Health Screening & Referral Program (WHSRP) was developed to address four important public health objectives: 1) to prevent unintended pregnancies, 2) to improve pregnancy outcomes by identifying health risks and assuring appropriate referrals both prenatally and during the preconception period, 3) to identify gaps in the existing services delivery system, and 4) to create a risk-responsive continuum of care for all women of childbearing age, regardless of pregnancy status.

Implemented in 1997 as a pilot project in several federally-funded Title X family planning clinics and private

OB/GYN practices, the WHSRP was expanded in 1998 to ten Title X family planning clinics, located in high-need communities with large concentrations of poverty. The clinics serve approximately 12,000 patients each year: 97% are women, 42% are from minority groups, 90% have family incomes at or below 150% of the federal poverty level (\$12,360 per year for a family of one), and 47% are uninsured. Medicaid covers 34% of patients.

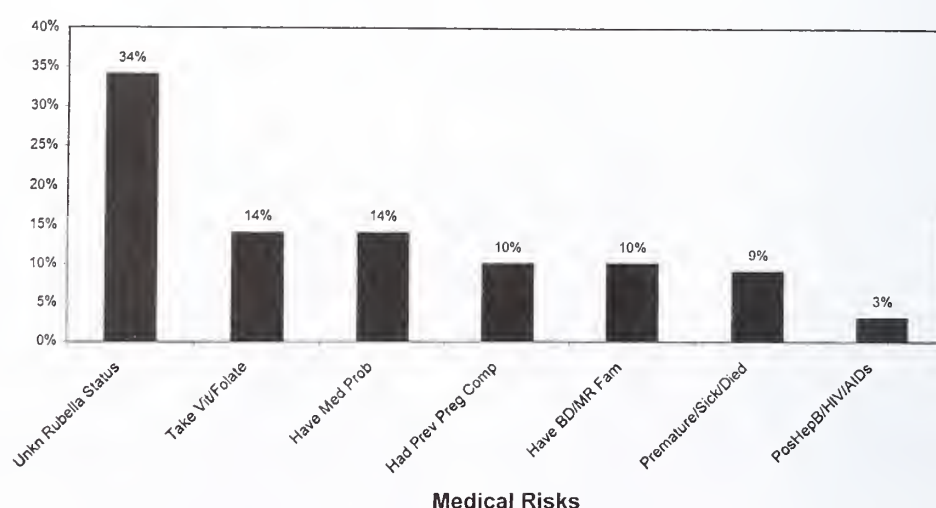
As a part of the WHSRP, all women at participating clinics can receive a pregnancy test at no cost to them. (If they have medical coverage for the service, it is billed to the third party. The rest are supported with federal Title V Maternal and Child Health funds). All women receiving pregnancy tests are asked to fill out a voluntary 18-item "Care Questionnaire" survey while they are waiting for the results of their test. The survey is available in English and Spanish.

Abbreviations Used:

EFNEP	Expanded Food and Nutrition Education Program
WHSRP	Women's Health Screening & Referral Program

The Care Questionnaire was designed by a partnership of family planning, obstetrical, and primary care professionals to flag significant risks to a woman's health and pregnancy status. Women who are identified with one or more health risks through the WHSRP are provided with education, and may be referred to any one of the following services, depending on their pregnancy status: family planning, smoking cessation, substance abuse assessment, nutrition services, social services, home visiting, domestic violence assistance, HIV/STD screening, mental health services, genetics counseling, community action programs, immunization, and medical or early prenatal care.

Figure 1
Care Questionnaires* (N=2,496)



*Care Questionnaires with site numbers or project numbers.

FINDINGS

Of the first 2,565 Care Questionnaires filled out at the 10 Title X family planning clinics in 1997 and 1998, 44% of the pregnancy tests were positive and 53% were negative. The results for about 3% were unknown at the time the survey was completed.

Although 80% of the 2,565 women reported that their suspected pregnancy was unplanned, only 34% were utilizing a birth control method at the time of the suspected conception. Still, 68% reported that, if their pregnancy test were positive, they would keep the baby with or without support from the baby's father.

The Care Questionnaire includes seven risks that can be considered "medical;" six, "behavioral;" and five, "socio-economic." In the "medical" risk category, 34% of the women reported that they did not know if they were immune to rubella, 14% reported that they had a variety of personal medical problems, and only 14% reported taking a multi-vitamin with folic acid (Figure 1).

In the "behavioral" risk category, 63% of these women reported that they smoked tobacco or were around others who did, 20% reported alcohol and/or drug use, and 14% had depressive or other mental health concerns (Figure 2). In the "socio-economic" risk category, 15% stated that they had no one to rely on at home and 13% reported transportation and/

or child care problems that affected their medical visits (Figure 3). Two percent of respondents voiced concerns about threats and violence.

Some of the "behavioral" health risks identified through the WHSRP were even more dramatic among women with negative pregnancy test results (Table 1). Of the 2,565 women who participated in the WHSRP, 1,330 tested negative. Of these women: 70%

said that they smoked tobacco or were around others who did, 25% that they used alcohol and/or illicit drugs, and 16% that they were depressed or had some other mental health concerns. Women with negative pregnancy test results also reported high rates of concern about nutrition or their diet (23%).

TABLE 1
NEGATIVE PREGNANCY TEST RESULTS
(N=1,330)

Behavioral Risks

86%	Are Not Taking Folic Acid
70%	Smoke or Are Around Others Who Smoke
25%	Are Using Alcohol and/or Drugs
23%	Have Concerns About Nutrition or Their Diet
16%	Are Depressed or Have Other Mental Health Problems
1%	Have HIV Risks

Medical Risks

35%	Do Not Know If They Are Immune To Rubella
16%	Have Personal Medical Problems
11%	Had Previous Pregnancy Complications
10%	Have Birth Defects or Mental Retardation in Family
9%	Had a Previous Newborn Who Was Premature or Sick or Who Died
3%	Are Positive For Hepatitis B, HIV, or AIDS

Socio-Economic Risks

15%	Have No One At Home to Rely On for Help With A Pregnancy
13%	Have Transportation And/Or Child Care Problems
7%	Do Not Have Enough Money For Food
4%	Do Not Always Have Utilities And/Or Phone Service
2%	Feel Threatened or Abused At Home

DISCUSSION

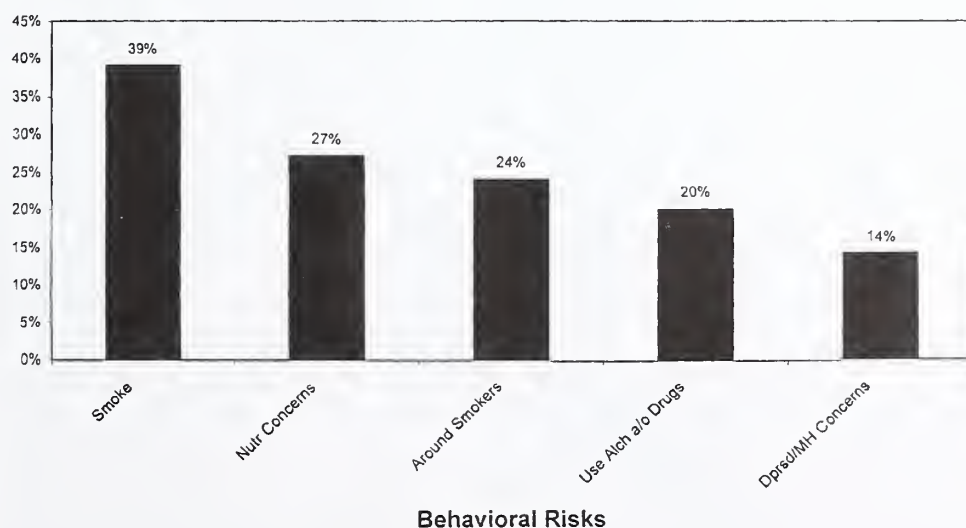
The WHSRP resulted in numerous referrals (Table 2). The WHSRP has identified several gaps in the existing continuum of care for women with negative pregnancy test results in Rhode Island. Many of the risks involve major opportunities for effective prevention:

FOLIC ACID

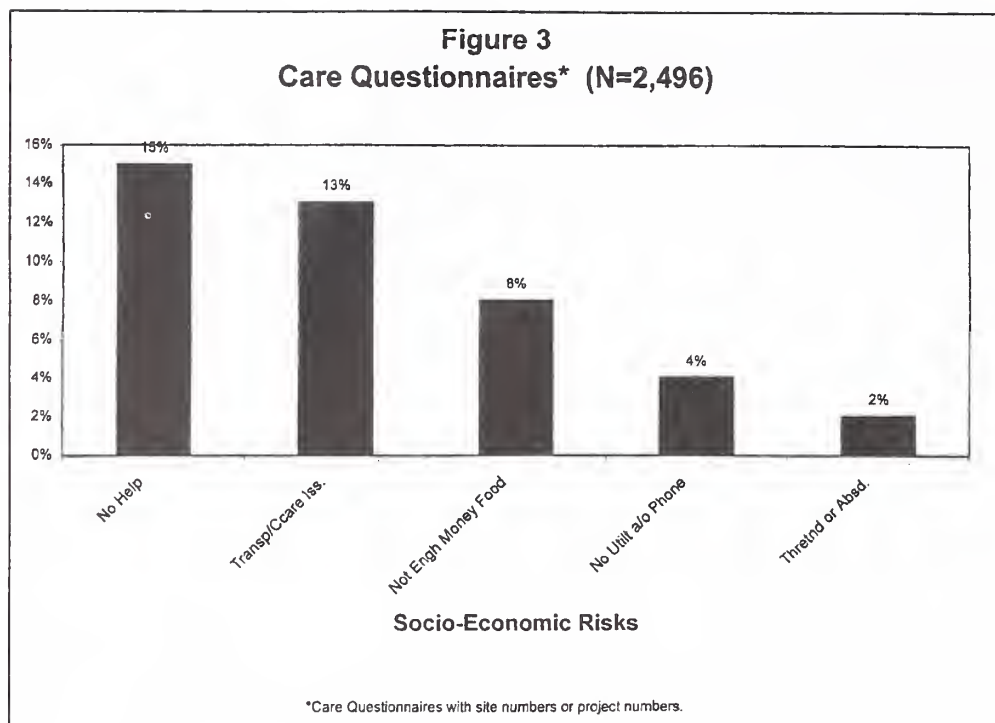
Folic acid can reduce the risk of certain birth defects that develop during the first few weeks of pregnancy, before many women suspect that they are pregnant. Presently, we recommend that all women ages 12-50 years, whether they are planning a pregnancy or not, consume 400 micrograms of folic acid daily to reduce the risk of those birth defects.

Many nonpregnant women do not know they should be taking folic acid. In a 1998 Gallup/March of Dimes national survey of 2,115 women ages 18 to 44 years, only 13% knew that folic acid could help prevent birth defects, and 7% that folic acid should be consumed prior to pregnancy. Fur-

Figure 2
Care Questionnaires* (N=2,496)



*Care Questionnaires with site numbers or project numbers.



ther, only 29% were taking a daily multi-vitamin containing folic acid when not pregnant. Pregnant women with health care coverage have prescriptions for prenatal vitamins. The Rhode Island non-pregnant women in this study, though, generally did not know they should be taking folic acid (available over the counter). Because half of these women will become pregnant within a year, it is critically important to develop strategies that alert non-pregnant, uninsured, poor women to the importance of folic acid, and to make it more accessible to them.

TOBACCO EXPOSURE

After years of declining tobacco use, over 200,000 adults still smoke cigarettes. Rates of smoking remain high among pregnant women (15%), and about 2,000 Rhode Islanders die prematurely from tobacco-related diseases each year.

Babies born to women who smoke while pregnant are at a higher risk for adverse outcomes, including low birthweight and prematurity. One in six women who give birth in Rhode Island smoked cigarettes while pregnant. Smoking during pregnancy is also associated with an increased risk of miscarriage, stillbirth, and infant death. Tobacco use by mothers (and fathers) can also adversely affect children after birth, since exposure to second hand smoke increases a child's risk

of asthma, pneumonia, and bronchitis.

Quitting smoking is notoriously difficult - fewer than 10% of the 15 million Americans who try to quit each year succeed. Studies indicate that 85% of smokers want to quit, and most try at least five times before they succeed. A number of studies have demonstrated the effectiveness in counseling in changing the smoking behavior of individuals, with increases in abstinence rates ranging from 3 to 25%.

Nicotine replacement therapies can also bolster smoking cessation. Studies have shown that 12-month smoking cessation rates double to 9 to 25% with the nicotine patch, and smokers who use the newer nicotine inhaler are twice as likely to quit as those using a dummy device. More recently, nearly half the smokers using the nicotine-free antidepressant Wellbutrin® for two to three months kicked the habit, compared with a quarter of those taking a placebo. Combining the antidepressant with the nicotine patch improved

the success rate to nearly 60%.

Many managed care programs in Rhode Island (including RItE Care) cover smoking cessation programs for pregnant women. But many non-pregnant, uninsured, poor women do not have ready access to these aids. The recent approval of federal tobacco settlement funds for community-based tobacco prevention efforts may provide Rhode Island with some new opportunities in this area.

NUTRITION

Good preconceptional nutrition improves pregnancy outcomes. Although 23% of the women with negative pregnancy test results who participated in the WHSRP reported concerns about nutrition or their diet, few had options to address their concerns. In Rhode Island, pregnant or breast-feeding women and children are eligible for WIC nutrition and food assistance. However, non-pregnant, uninsured, poor women have fewer opportunities to access nutrition education services.

In fact, in Rhode Island few nu-

TABLE 2
WHSRP REFERRALS

Type of Referral	Number of Referrals
Family Planning	1,389
Adolescent Self-Sufficiency or Town Teen Network Program	35
Prenatal/Early Prenatal Care	992
Medical Provider	17
RItE Care	145
Nutrition Services, including WIC	1,756
Home Visiting Services	117
Social Work Services	242
Community Action Program	24
Tobacco Cessation	481
Substance Abuse	47
Domestic Violence	34
Genetic Counseling	69
Mental Health Services	61
HIV Screening	53
Immunization	195
Education	
Tobacco	637
Substance Abuse	2
Nutrition	235

trition programs specifically target low-income women without children. Rhode Island's Expanded Food and Nutrition Education Program (EFNEP) helps urban, low-income families to acquire knowledge, skills, and changes in behavior to achieve nutritional diets. Low-income families in the state's non-urban (and some urban) communities are not eligible for EFNEP. The Rhode Island Community Food Bank operates a basic nutrition education workshop, Eating Right, for low-income individuals on a limited basis. Rhode Island's Home Visiting Program, which includes a nutrition education component, does not presently serve non-pregnant women.

TEENS

Of the 2,565 women who participated in the WHSRP, 10% were adolescents. The suspected pregnancy was unplanned for 92% of the 256 adolescents who completed Care Questionnaires. Adolescent girls with a negative pregnancy test result are a priority target group for pregnancy prevention intervention. Of the 256 adolescents who participated in the WHSRP, 66% had a negative pregnancy test result.

In Rhode Island, the Department of Human Services funds Adolescent Self-Sufficiency Programs to help prevent repeat pregnancies among pregnant and parenting girls, and the Starting Right child care initiative includes funding for adolescent after-school programming, which will include youth development opportunities and pregnancy prevention strategies. However, there are few opportunities for adolescent girls who are clearly sexually active, but not yet

Although 80% of the 2,565 women reported that their suspected pregnancy was unplanned, only 34% were utilizing a birth control method at the time of the suspected conception.



pregnant, to receive the intensive follow-up and support services that many adolescents need to avoid unintended pregnancy. The state has started a serious discussion of youth success strategies, including after school programs, school-based health services, and community mentoring to protect the health and school success of these adolescents.

CONCLUSION

The WHSRP is well-accepted and identifies significant preventable health risks at the time of pregnancy testing. The expansion of Medicaid managed care in Rhode Island seeks to improve the health of pregnant women and their

babies. However, many of the risks are best addressed before conception, and non-pregnant, uninsured, poor women do not have the same opportunities that pregnant women have to address identified risks.

Some of those risks pose major preventive opportunities, such as the use of folic acid prior to conception, smoking cessation, nutrition education, and adolescent pregnancy prevention. However, non-pregnant women (especially those who are uninsured and poor) often have difficulty accessing such services in Rhode Island. In our efforts to prevent unintended pregnancy and improve birth outcomes, we must focus on all women, pregnant and non-pregnant.

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Water Systems to Report Drinking Water Quality to All Customers: How Can Health Professionals Prepare for the Questions That These Reports Will Generate?

Kathleen McCarty, June Swallow, PE, Robert Vanderslice, PhD, Walter S. Combs, Jr, PhD

CONSUMER CONFIDENCE REPORTS: WHAT ARE THEY? WHY ARE THEY IMPORTANT TO PHYSICIANS?

Annually, beginning in October 1999, Rhode Island residents on public water supplies will receive Consumer Confidence Reports (CCRs) either in the mail, along with their water bill, or through their local newspaper. These brief annual water quality summaries include data on contaminants in the water. The Rhode Island Department of Health (HEALTH) expects that patients will look to physicians for guidance in interpreting these reports. This article provides information about CCRs and public drinking water systems to help physicians answer their patients' questions.

HEALTH oversees the quality of drinking water in Rhode Island and assures that water systems comply with safe drinking water requirements. HEALTH also regulates bottled water in Rhode Island. To ensure the safety of drinking water in the state, HEALTH not only tests thousands of water samples each year but also conducts comprehensive inspections of the water systems, including the drainage areas around water sources and the treatment, storage and pumping facilities. HEALTH maintains databases on public water systems and is able to provide engineering and health effects expertise. HEALTH also has extensive contacts with federal agencies concerned with public health and can assist in interpretation of state and federal laws relating to public health.

CCRs are a provision of the Safe Drinking Water Act, amended in 1996.¹ The United States Environmental Protection Agency (USEPA) intends CCRs to inform consumers about any contamination in their drinking water and to increase aware-

ness about the importance of protecting drinking water sources from inappropriate development. CCRs include information on the sources of drinking water, definitions of key terms, data on levels of contaminants in drinking water, explanations of compliance with other drinking water regulations, and required educational information. CCR regulations apply to new and existing community water systems, that is, public water systems that provide piped water to at least 15 service connections or are utilized by 25 residents daily. In Rhode Island there are 90 public water systems, serving more than 90% of the population, that are required to write CCRs. In addition, the two systems that provide drinking water for 100,000 or more consumers (the Pawtucket Water Supply and the Providence Water Supply) must post their CCRs on the Internet.

INTERPRETING THE CONSUMER CONFIDENCE REPORTS

In Rhode Island drinking water from public supplies is safe for consumption, except in unusual circumstances. On occasion, bacterial

Most people do not realize that they are exposed to the chemicals listed in the CCR from a variety of sources, and that their drinking water may contribute only a small percentage of their total exposure.



Abbreviations Used:

ATSDR	Agency of Toxic Substances and Disease Registry
CCR	Consumer Confidence Reports
FDA	Food and Drug Administration
HEALTH	Rhode Island Department of Health
USEPA	United States Environmental Protection Agency

contamination has occurred, and HEALTH has worked with the water suppliers to publicize, and correct, the problem. All public water supplies are regularly tested by HEALTH or by the suppliers themselves. Contaminants reported on the CCR at levels below the standard levels are safe and are not known to result in any health effects.

HEALTH asks that health care providers look upon CCRs as an opportunity to discuss their patients' concerns about exposures to chemicals, especially from sources other than drinking water. Ideally, patients will then evaluate their own behaviors and identify how they can best limit their exposures to chemicals of concern.

Most people do not realize that they are exposed to the chemicals listed in the CCR from a variety of sources, and that their drinking water may contribute only a small percentage of their total exposure. The contaminant levels reported on the CCRs are likely to be within the safety standards but will probably not be at zero. Figure 1 provides some information on common compounds that will be reported on the CCR at trace levels but also exist in our everyday environment. For example, patients could more effectively decrease their exposure to benzene by quitting smoking, storing benzene-containing compounds such as gaso-

Figure 1: Common Environmental Exposures Equivalent to Maximum Potential Daily Drinking Water Exposureⁱ

CHEMICAL ⁱⁱ	DRINKING WATER STANDARD	MAXIMUM POTENTIAL DAILY DRINKING WATER EXPOSURE ⁱⁱⁱ	OTHER COMMON SOURCES OF EXPOSURE	EQUIVALENT EXPOSURE ^{iv}
VOLATILE ORGANIC CHEMICALS (VOCs)				
Benzene	5 ppb	10 µg	Gasoline fumes Tobacco smoke	Traveling by car for 15 minutes Smoking 1/5 cigarette
1,1,1-Trichloroethane	400 ppb	800 µg	Solvent fumes (occupational exposure) Solvent fumes (consumer products)	Workroom air for <1 minute Use of oven cleaners, auto products, etc.
HEAVY METALS				
Lead	15 ppb (action level)	15 µg (for a child)	Pre-1978 house paint Urban dust	Chip no larger than a child's fingernail 3 square inches of dust on a lead-safe windowsill
Arsenic	50 ppb	100 µg	Typical RI soil Diet (esp. seafood)	Routine exposures for a child during outdoor play for a year Dietary exposure over 2 days
OTHER CHEMICALS				
Fluoride	~1 ppm is the optimal level	1 mg	Diet Supplements	Inadequate to reach optimal levels Often prescribed for children receiving drinking water which isn't fluoridated
Nitrate	10 ppm	20 mg	Adult diet	One serving of vegetables (spinach, cauliflower, etc.) Nitrate/nitrate is primarily of concern for infants who receive little dietary nitrate.

ⁱ These are "worst case" scenarios. Public water supplies in Rhode Island typically have levels that are far less than maximum allowable levels of contamination.

ⁱⁱ With the exception of nitrate, summary information on these chemicals can be obtained from the ATSDR website www.atsdr.gov/toxfaq.html. More detailed information can be obtained from the Toxicological Profiles for these chemicals. Complete citations are included in Reference 2 at the end of this article.

ⁱⁱⁱ Total intake from consuming 2 liters per day of water, which contains that chemical at the drinking water standard.

^{iv} Common activities, which produce exposures, approximately equivalent to that obtained from daily water consumption at the drinking water standard.

line and paints in a storage shed outside of their homes, and using full service gasoline stations. Additional information on CCR chemicals can be obtained from the ATSDR Toxicological Profiles.² Information specific to fluoride may be found in Kaminsky et al.³

Lead and copper will appear on a CCR. Lead and copper levels result from lead pipes and lead-soldered copper pipes in plumbing and distribution lines. Lead levels can be reduced simply by allowing water to run through the pipes for a few minutes before using it. This flushes the lines and brings in fresh water from the distribution line. Lead exposure can also be reduced by only using cold water for drinking or cooking, since heat will increase the dissolution of lead into water. To prevent childhood lead poisoning, parents must protect their children from the hazards of lead-based paints. Concerned parents can learn more about protecting their children from lead by contacting HEALTH.

Patients may be concerned over the terminology used in the

required health effects language as determined by the USEPA. These reports will contain the following statement, "Some people may be more vulnerable to contaminants in drinking water than the general population. Immunocompromised persons such as persons with cancer undergoing chemotherapy, persons who have undergone organ transplants, people with HIV/AIDS or other immune system disorders, some elderly, and infants can be at risk from infections." This language is required because tap water is not sterile, and neither is bottled water. Individuals who need sterile water must boil their drinking water no matter what the source. It is essential that individuals understand that while the water might pose a challenge to immunocompromised persons, it is safe for the general public. If patients are concerned that their drinking water is not sterile, perhaps the following analogy will be helpful. Clothes fresh off the clothesline are considered fresh and clean, but they are not sterile.

Home Treatment Devices and Bottled Water Facts

Persons who are considering using home treatment devices or bottled water because of the trace levels of contaminants reported in the CCR should know the following about bottled water and home water filters:

- The standards for regulation of bottled water are practically the same as for public drinking water. Bottled water is regulated as a food product by the FDA, while tap water is regulated by the EPA. Both are regulated by HEALTH.
- A large number of people drink bottled water because they prefer the taste. However, the taste of tap water can be improved by refrigerating it,
- Bottled water is much more expensive than tap water. A person who drinks 2 liters of bottled water per day spends \$15 to \$45 per month.
- Water filters are recommended only when contaminant levels exceed established standards.
- Proper maintenance of home treatment devices is essential for ensuring a safe supply.

Figure 2: Resources for Health Care Providers

TYPE OF INFORMATION NEEDED BY HEALTH CARE PROVIDERS	RECOMMENDED REFERENCE SOURCE
General information on Consumer Confidence Reports	http://www.epa.gov/safewater
Information about interpreting CCRs	Purdue University Cooperative Extension Service Phone: (765) 494-8422 Email: fourh@four-h.purdue.edu
Expertise on drinking water specifically in Rhode Island	The Rhode Island Department of Health website: http://www.health.state.ri.us The USEPA website on drinking water in Rhode Island: http://www.epa.gov/OGWDW/dwinfo/ri.htm
Point of contact for Expert Consultation	June Swallow, P.E., Chief State of Rhode Island Department of Health Office of Drinking Water Quality Three Capitol Hill, Room 208 Providence, RI 02908-5097 Phone: (401) 222-6867 Fax: (401) 222-6953 Robert R. Vanderslice, Ph.D. State of Rhode Island Department of Health Environmental Health Risk Assessment, Chief Three Capitol Hill, Room 208 Providence, RI 02908-5097 Phone: (401) 222-4948 ext. 2103 Fax: (401) 222-6953
Additional information on symptomatic patients from national experts qualified to provide medical advice	Agency for Toxic Substances and Disease Registry(ATSDR) Phone: (800) 447-1544 http://www.atsdr.cdc.gov/toxfaq.html
Family Health Information Line for parents to learn more about lead and their children's health	(800) 942-7434



The standards for regulation of bottled water are practically the same as for public drinking water.



sheds and wellheads.

The Consumer Confidence Reports are meant to inform consumers about their drinking water supply. Consumers should use the reports to verify that their drinking water meets all health standards and to understand some of the potential threats to their drinking water quality. Physicians may use the reports as an opportunity to discuss the many types of environmental exposures and ways to reduce these exposures. As a crucial component of the public health community, this is your opportunity to encourage your patients to become more aware of their environment and its impact on their health.

REFERENCES

- 1 National Primary Drinking Water Regulations: Consumer Confidence Reports, 40 CFR Parts 141 and 142. Originally published 19 August 1998 (63 FR 160, pages 44511-44536). [Internet: www.epa.gov/safewater/ccr/ccrfact.html]
 - 2 The Toxicological Profiles for the chemicals listed in Figure 1 are available, for a fee, from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 [Phone: (800) 553-6847 or Internet: www.ntis.gov]
- *Toxicological Profile for Benzene (Update), 1 September 1997, U.S. Department of Health & Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. [NTIS #: PB/98/101157/AS]
- *Toxicological Profile for 1,1,1-Trichloroethane (Update), 1 August 1995, U.S. Department of Health & Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. [NTIS #: PB/95/64396/AS]
- *Toxicological Profile for Lead (Update), 1 July 1999, U.S. Department of

Health & Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. [NTIS #: PB/99/166704/AS]

*Toxicological Profile for Arsenic (Draft), 1 September 1998, U.S. Department of Health & Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. [NTIS #: Not Available-Contact ATSDR]

*Toxicological Profile for Fluorides, Hydrogen Fluoride, and Fluorine (Update), 1 April 1993, U.S. Department of Health & Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. [NTIS #: PB/93/182566/AS]

3. Kaminsky LK, Mahoney M, Leach J, et al. Fluoride Benefits & Risks of exposure. *Oral Bio & Med* 1990;1:261-81.

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Nor do they need to be for general purposes. But bandages for cuts do have to be sterile in order to reduce the chances of infection. Water that is safe for consumption by the general public is not sterile, but is safe. Immunocompromised individuals, on the other hand, have to take extra precautions to preserve their health since they are more susceptible than the general public.

Patients may link their symptoms to the contaminants reported in the CCR. But the trace levels of chemical contaminants in Rhode Island public drinking water supplies would not be expected to cause acute symptoms. Physicians can assure patients that drinking water standards are created to protect against health effects after lifetime exposure to 2 liters of water per day and can continue to advocate that people consume 8 glasses, or 2 liters, of water per day in order to maintain proper hydration. Figure 2 presents several informative resources for CCR reports, drinking water in the State of Rhode Island, and contact information for the Agency of Toxic Substances and Disease Registry (ATSDR) on exposure to these chemicals and symptomatic patients.

SUMMARY

The ultimate safety of drinking water depends upon protection of source waters and construction and maintenance of reliable drinking water treatment and distribution systems. These objectives require public support. Physicians can encourage their patients to call their water suppliers and advocate for investment in effective treatment systems and support zoning that will protect water supply water-

Utilization Review: A Practical Approach for Physicians

Donald C. Williams, MA, and Luis M. da Costa

OVERVIEW OF MANAGED CARE REGULATION IN RI

The Rhode Island Department of Health's (HEALTH) Office of Managed Care Regulation (OMCR) has statutory and regulatory jurisdiction over health maintenance organizations (HMOs), utilization review (UR) agencies, and health plans (HPs) through the State of Rhode Island's Rules and Regulations for the Assessment of Health Care Services of Health Maintenance Organizations (R27-41-HMO), the Rules and Regulations for the Utilization Review of Health Care Services (R23-17.12-1-UR), and the Rules and Regulations for the Certification of Health Plans (R23-17.13-CHP). This article seeks to provide physicians with a brief overview of managed care regulation in Rhode Island with emphasis on UR and how physicians may utilize this regulatory program to provide medically necessary covered services to their patients.

THE HP PROGRAM

OMCR's HP Program, which includes the oversight of HMOs, assures availability, access, quality, and continuity of care through health plan certification, consumer disclosure, provider due process, and complaint investigation. A health plan provides for the delivery of health care services to enrollees. It contracts with selected providers to deliver health care services, and enrollees are given financial incentives to use their health plan's participating providers and covered procedures. The specific services included under the patient's health care contract with the insurer are called "covered services." Presently, there are 26 health plan entities (58 certified health plans), of which 6 are also certified as HMOs.

UTILIZATION REVIEW:

The Definition, The Program, The Process

The regulatory definition of Utilization Review is "the prospective or concurrent assessment of the necessity and appropriateness of the allocation of health care resources and services of a provider, given or proposed to be given to a patient or group of patients." UR, more practically defined, is a review of a physician-ordered service to determine whether the service rendered or to be rendered is medically necessary and, therefore, covered for payment. UR may be applied to review of covered services only. A health plan cannot be made to pay for a non-covered service, even if a physician thinks the service is necessary. Utilization Review enables health plans to control costs.

Through its regulatory authority to certify UR agencies and ensure their compliance with state requirements, OMCR attempts to guarantee access, quality, and continuity of care. In Rhode Island, any entity performing UR must be certified with HEALTH as a UR agency. If an uncertified UR agency is found performing UR, administrative action to secure compliance will be taken. Currently, fifty-eight UR agencies are certified within the state.

UR may be performed prospectively, concurrently, or retrospectively. In the past, only prospective and concurrent reviews were regulated under Rhode Island General Law, but recently, Chapter 17.12 of the Rhode Island General Laws, Health Care Services - Utilization Review Act has been amended to cover retrospective review as of January 1, 2000.

A "prospective" (or prior-authorization) review for medical necessity is conducted before the services are rendered

"Concurrent" review takes place while the services are being rendered.

Abbreviations Used:

CHDR	Center for Health Dispute Resolution
HEALTH	Rhode Island Department of Health
HMO	health maintenance organizations
HP	health plan
MassPRO	Massachusetts Peer Review Organization
OMCR	Office of Managed Care Regulation
UR	utilization review

"Retrospective" review takes place after the services are delivered.

Adverse Determination/Decision not to Certify

The regulatory definition of an adverse determination is "any decision by a review agent not to certify an admission, service, procedure, or extension of stay [medical action]; provided, however, that a decision by a reviewing agent to certify an admission, service, or procedure in an alternative treatment setting, or to certify a modified extension of stay, shall not constitute an adverse decision if the reviewing agent and the requesting provider are in agreement regarding the decision." If the UR agency determines that a patient's medical care is unnecessary, no alternative medical action is agreed upon, and payment is denied, then this decision not to certify is referred to as an adverse determination. The patient, someone on the patient's behalf, the attending physician, or another provider may appeal an adverse determination.

Requirements for an Adverse Determination

All adverse determinations must be made, signed, and documented by a qualified physician, defined as "a licensed practitioner with the same licensure sta-

tus as the ordering practitioner or dentist or a licensed physician or dentist in the same or similar specialty, which usually manages the procedure in question.” The UR agency’s qualified physician must discuss with the attending physician the decision not to certify, before the determination. If the attending physician is not reasonably available, then the reviewing physician can make an adverse determination, but must show documentation of the unsuccessful efforts to contact the attending physician. Therefore, if the physician feels that his/her medical decision is necessary for the patient, then the physician must make himself/herself available to discuss/defend that decision. The physician ought to compile as much clinical information as possible when refusing a UR denial because the more clinical information the ordering physician provides supporting his/her clinical rationale, the stronger and more substantiated the case will be. The decision to provide treatment or service, and which treatment or service is best suited for the patient, is the responsibility of the attending physician and the patient. After an adverse determination, the patient and/or provider is entitled to two levels of internal appeal. The review agency is obligated to inform the patient and provider of the internal appeal procedure.

Request for Review and Notification of Decision

A written or verbal request made by or on behalf of a patient for an evaluation of a medical action needs to show the urgency for a response. If a request is made verbally, it also must be submitted in writing to the review agency within seven days. If the UR agent denies certification of and payment for a medical action due to lack of medical necessity, the review agent must notify the attending physician and the individual patient of its adverse determination within one

business day after receiving all information necessary to complete the review. All information to be reviewed by the UR agent must be relevant to the UR process, and individual medical records must be kept in strictest confidence. In the case of a concurrent determination, notification of denial must be sent out no later than one business day before the current certified period of treatment expires. Written communication of an adverse determination must include:

- a) the principal reasons for the adverse determination,
- b) the procedures to initiate an appeal of the denial,
- c) the telephone number of the contact person for the appeal, and
- d) a reasonable time period to file an appeal.

Each UR agency is obligated to explain the criteria for medical necessity evaluation used to make their decisions when reviewing a case.



INTERNAL APPEALS PROCESS: TWO LEVELS

A clear understanding of the appeals process is imperative for physicians to advocate for their patients’ medical needs and their own clinical judgment. Sections 6 and 7 of the UR Regulations set the standards for the internal and external appeals process respectively. Rhode Island General Law mandates that each Rhode Island certified UR agency offer two levels of internal appeal. The review

agent has 15 business days to inform the attending physician and the patient in writing of the first level appeal decision. If verbal communication is given within 15 business days, the written notice is to be

made no later than 21 business days. If an appeal has been defined as an emergency, then an expedited review (at either the first or second level internal appeal) must be initiated and completed within 2 business days.

If the first appeal decision is unsatisfactory to the appealing party, then the UR agency must afford the appealing party the second level of internal appeal. The appealing party will have the opportunity to inspect the UR file and add information in writing before a final decision at the second level of appeal is reached. If additional information is to be added, it must be done in compliance with all state and federal laws which protect the confidentiality of medical records. The UR agent may not add any new information requirements. The appealing party may merely request that the existing information be re-evaluated.

The second level appeal decision must be furnished to the patient and provider within 15 business days after receiving all case related information. If verbal notice is given within 15 business days, then written notification must be made no later than 21 business days. The appealing party must be informed of the availability of the two state-designated external review agencies and the means for initiating an external appeal. Unlike both levels of internal appeals, which are free, the external review agencies charge a fee for reviewing a case. Typically, the appellant’s cost of a non-psychiatric service denial averages \$200 while the cost of an appeal of a psychiatric service denial averages \$250.

EXTERNAL APPEALS PROCESS: TWO CERTIFIED AGENCIES

The HEALTH designates 2 independent external review agencies, the Center for Health Dispute Resolution (CHDR) and the Massachusetts Peer Review Organization (MassPRO). These agencies are independent of the UR agencies, the HEALTH, and the parties involved. When requesting an external review, the appealing party must contact the UR agency in writing within sixty days after being informed of the second level denial. A check payable to the external review agency for one half of the predetermined fee (which includes all ad-

Table 1
UR Appeals Summary, 1998

30 %	of all prior and concurrent authorizations were appealed
19%	of those appeals were overturned at the first level
26%	of the appeals that went to second level were overturned
42%	of appeals reviewed by an external agency were overturned

ministrative costs and the cost of the reviewing clinician) must be attached to the written request in order to begin the external appeals process. The UR agency pays the other half of the fee.

After receiving the request and check from the appealing party, the review agent has 5 days to send to the external review agency (CHDR or MassPRO):

- the complete file upon which the adverse decision was based including the specific findings of the adverse determination,
- the specific review agency criteria utilized in rendering the adverse determination, and
- documentation that payment has been authorized for the pre-determined fee of the external review.

Upon receipt of all necessary information and full payment for the review, the external appeals agency has 2 business days to make a final determination for expedited appeals and 10 business days for all other non-emergency (standard) appeals.

The external review agency must base its decision on the criteria for medical necessity denial used by the UR agency, as well as the medical necessity and appropriateness of the medical action. Notice of this decision, which is final and binding, will be sent to the patient and his/her physician, and will include the rationale for the determination. Pursuant to amendments made this year to the UR Act, after January 1, 2000, the appealing party will receive a refund from the UR agent of its portion of the external appeal fee if the external agency overturns the UR agent's denial of coverage. Judicial review is the only other option afforded to any party still aggrieved by the decision.

RESTRICTIONS ON REVIEWER

Certain restrictions and obligations are placed on the reviewer. For instance, a reviewer cannot receive any type of financial incentive to uphold an adverse determination. Also, if a reviewer has been involved in the prior review of a case or in the direct care of the patient, s/he is not allowed to be the sole reviewer

of the same case under appeal. If information is added, the initial reviewer who made the adverse determination may conduct the first level appeal. The UR agent must be accessible to patients, patients' families, and physicians at least 8 hours per each business day in Rhode Island, from 7:00 AM to 6:00 PM.

CRITERIA

Each UR agency is obligated to explain the criteria for medical necessity evaluation used to make their decisions. Screening criteria and review procedures for medical necessity assessments are to be established with the input of local physicians. Opportunities must be made available for review and comment from local physicians. Physicians can be proactive in the UR process by joining a UR agency's advisory board. Physicians may also request to review the criteria that are used by the utilization review agency. If the physician is dissatisfied with the criteria, then s/he ought to bring it to the attention of the UR agencies and the HEALTH.

PRESCRIPTION MEDICATION

If the attending physician prescribes medication that is not on the health plan's formulary, per Rhode Island Law, a patient or the attending physician is allowed to appeal for coverage of that specific drug. In order to appeal, the attending physician must show that the medication prescribed is medically necessary for the patient. When the non-formulary medication meets the health plan's medical exception criteria, coverage must be given. The health plan's medical exception criteria must be in accordance with Section 3(c)(3) of the Rhode Island Rules and Regulations for the Certification of Health Plans (R23-17.13-CHP).

COMPLAINT RESOLUTION

In response to a written complaint, the HEALTH has the authority to review any internal or external appeals processes regarding adverse determinations. In order to respond adequately to the complaint, the HEALTH may request that the review agent, the provider, or patient submit, in writing, information on the status, processing, outcome, and rationale of the decision in question. OMCR's UR Program sets reporting re-

quirements for UR agencies and allows for complaint investigation.

SUMMARY

Rhode Island has rules and regulations for UR, as well as an appeals process. When the appeals process is used, it is more often than not successful. (Table 1) If questions arise concerning the UR Act, the UR process, the appeals process, the rights of patients, physicians, and reviewers, or the authority of the HEALTH, please contact OMCR. For a copy of the Rules and Regulations for the Utilization Review of Health Care Services (R23-17.12-1-UR), please write: Rhode Island Department of Health Office of Managed Care Regulation 3 Capitol Hill Cannon Building, Room 410 Providence, RI 02908

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Communicating Public Health Via the Internet in RI: www.health.state.ri.us

Robert J. Marshall, Jr, PhD, and Barry Levin

The United States claims more Internet users than any other country (an estimated 133 million in 2000).¹ Usage increased dramatically over the last 5 years. In Rhode Island, the number of adults with computers at home rose modestly from 43% to 49% between 1996 and 1999, but the percent of them who access the Internet from a computer at home nearly doubled from 39.6% to 75.2%.² As of February 2000, most US workers (80%) report using e-mail and word processing at work; 77% browse the Internet at work.³

The US also contains the largest proportion of people who use the Internet to search for health information. According to the Georgia Institute of Technology's 10th annual user survey, more Americans use the Internet for health information than users in Europe and other areas. (Figure 1).⁴ More than 42% of US users access health information via the Internet at least monthly. By one account 17.5 million US adults use the Internet for this purpose.⁵ Researchers also found that 81% of consumers who go online for health information say the informa-

tion is "either useful or very useful."

Consumers turn to the Internet, in part, because of what they regard as a lack of information from traditional sources. They want to make informed decisions about their health care. They prefer not to remain dependent solely on professional advice; they want to uncover the information themselves. As a result, new websites, such as DrKoop.com and WebMD.com attract millions of inquiries each day.

Web-based health information is distributed unevenly through the population. Persistent, even expanding gaps between the access of racial and ethnic groups to the Internet present a nagging problem. According to a US Department of Commerce survey,⁶ 44% of whites own computers compared to 20% of blacks, 25.5% of Hispanics and 55% of Asians. Among families earning \$15,000 to \$33,000, more than 33% of whites owned computers compared to 19% of African Americans. Furthermore,

Abbreviations Used:

CDC	Centers for Disease Control and Prevention
HARI	Hospital Association of Rhode Island
HEALTH	Rhode Island Department of Health
HPHC-NE	Harvard Pilgrim Health Care of New England

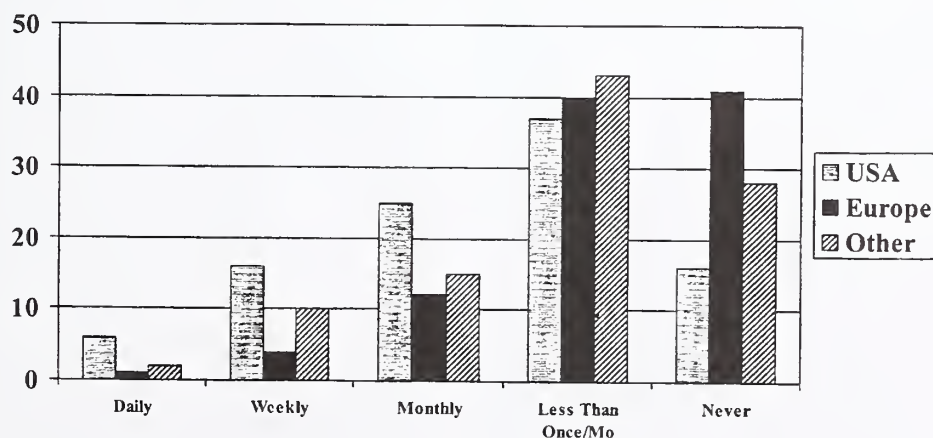
the gap increased 62% since 1994—despite plunging computer prices. The survey report recommends providing online access at community centers, schools, libraries and other public facilities, to compensate for lack of home access.

Physician use of the Internet presents quite a different picture: 85% of US physicians surveyed in 1999 reported using the Internet - an increase of 875% compared with 1997.⁷ Nearly two thirds of physicians used e-mail daily and one third communicated with patients via e-mail in 1999 - a jump of 200% over 1998. E-mail communication with patients did not even register on previous surveys of physicians. In 1999 one-third of US physicians and group practices maintain websites, with an additional 16% planning to establish a site within the next year.

The Internet is fast becoming the predominant source of health information and communication for health professionals as well as the public. It also provides a useful tool for state and local officials to communicate with physicians and the public about health issues. It gives practicing physicians an easy way of staying up-to-date on local health issues and provides a place to refer inquiring patients who need credible sources of information about health in their own community.

Keeping the connection current takes time and effort. Like other areas

Figure 1
Percent Who Use the Internet
for Medical Information
USA, Europe and Other Areas



Source: GVVU's 10th WWW User Survey (October 1998) Copyright 1998 GTRC

of health, public health information changes constantly. For the first time, the *Healthy People 2010 Objectives for the Nation*⁸ contains a goal on health communications, "Improve the quality of health-related decisions through effective communications." It defines health communications as "the art and technique of informing, influencing and motivating individual, institutional and public audiences about important health issues. Its scope includes disease prevention, health promotion, health care policy and business, as well as enhancing the quality of life and

health of individuals within the community."

In anticipation of the emerging role of health communications, the Rhode Island Department of Health (HEALTH) established public health information and expertise as its two "key strategic assets." Transforming public health data into information which is accessible and usable by the general and professional public continues to be a challenge. Like other health fields, public health knows that books and reports alone fail to satisfy the public's demands for timely informa-

tion. The Internet provides an alternative with video, audio and interactive data analysis as options for future development.

Rhode Island Department of Health (HEALTH) Website:
www.health.state.ri.us

Launched in late 1998, HEALTH designed its website to fulfill distinct functions corresponding with the "essential services of public health."⁹ (Table 1) The HEALTH website directs information to health professionals, media, general public and community audiences depending on the issue and the type of intervention needed (community mobilization or physician advisory). Since its inception, the website provides a key resource for communicating public health information, highlighted in these three vignettes.

Meningitis in Rhode Island (1998): Diagnosing health problems and mobilizing community action

The unexpected rise in meningococcal cases in Rhode Island during the first seven weeks of 1998 caused the deaths of three children and precipitated a statewide panic. Anxious families gridlocked hospital emergency rooms and physician offices throughout the area. Responding to the crisis involved maintaining continuous and nearly instant communication with at least four distinct audiences: community physicians, media outlets (press, TV, radio), general public, and local organizations, including hospitals, schools and city/town government. In addition to faxing documents to long lists of recipients, HEALTH used the Internet to get information out quickly and efficiently.

By the first week in March 1998, the increased availability of public health information began to allay public anxiety and turn panic into an organized community response. Over the next several weeks, local organizations, such as hospitals and schools, immunized over 200,000 children and youth through more than 150 community clinics. Although no additional confirmed cases of meningococcal disease occurred during 1998, the episode be-

Table 1
Selected HEALTH website materials corresponding to essential services of public health

Essential Services of Public Health	HEALTH Website Components
Monitor the population health status	Epidemiology surveys and reports Cancer registry Reportable diseases (meningitis) Childhood lead poisoning Food Insecurity Minority health data
Diagnose and investigate health problems and hazards	Environmental monitoring Beaches, restaurants, dioxin Health promotion advisories (smoking, obesity)
Mobilize Community Action	Media releases (flu vaccine clinics) City/town specific data Teen tobacco use Healthy Schools, Healthy Kids Health Policy Briefs (uninsured population)
Inform, Educate and empower people about health issues	Communicable disease alerts (EEE, arsenic, rabies, Lyme disease) Topical index Disease specific information Newsletters New information("hospitalists")
Enforce laws and regulations to protect health and ensure safety	Health Regulations Public hearings/announcements
Evaluate effectiveness, accessibility and assure quality	Consumer's Guides to Health Plans Profiles: Nursing Homes, Physicians, Health Plans, JCAHO data on hospitals. Community Benefits Study Monitoring Uninsured Rhode Islanders
Link people to needed services	Clinic schedules (flu, meningitis, AIDS) Translated materials (Spanish, Portuguese) Health Programs and Services Family Health Information Line

Table 2
Audience and Meningitis-related materials on the
HEALTH website

Audience	Internet-provided materials
Community physicians	Vaccine Provider Updates Vaccine Policy
Media	Press releases and Media Updates
General public	Advisories
(English, Spanish, Portuguese, Hmong, Laotian)	Fact sheets, questions and answers Prevention guidance
Local organizations/government	Clinic schedules

came a RI model for organizing community responses to communicable disease and for providing public health information. Rhode Island received a 1998 National Health Information Award for its use of the HEALTH website during this crisis.

HEALTH CARE QUALITY: ENSURING ACCESS AND QUALITY

Getting information about health care providers and services is easy, but knowing if the information is objective and credible often proves more difficult. The HEALTH website provides information on quality for several of the major components of the health care system in Rhode Island - including physicians, nursing homes, hospitals and Health Plans.

Physicians

Physician profiles on the Internet stem from 1997 law (RIGL 5-37-9.2) requiring HEALTH to provide information on all physicians licensed in Rhode Island. Presented under the name "RI DocFinder," the listings include license status, board certification, medical school, hospital privileges and any findings of unprofessional conduct in Rhode Island. Future editions of these profiles expect to have information regarding malpractice judgments and other information provided by the Board of Medical Licensure and Discipline.

Nursing Homes

More than 100 nursing homes operate in Rhode Island. Comparisons are not easy; giving advice about nursing home choices to patients' families

Nearly two thirds of physicians used e-mail daily and one third communicated with patients via e-mail in 1999 - a jump of 200% over 1998.



can be just as challenging. HEALTH's website offers consumers and physicians objective and credible data about nursing home quality. HEALTH's Division of Facilities Regulations inspects nursing homes every 9-15 months to assess compliance with federal and state regulations. In unannounced inspections, licensed and trained health professionals look at 88 items in five areas: administration, nursing care, resident rights, kitchen/food service and environment. The system generates a current report after each new survey. Consumers can use reports based on these data to compare a nursing home's general performance with that of other nursing homes. For more detailed information, consumers can link directly with the Health Care Financing Administration (HCFA) Nursing Home Database. This site tells consumers how serious and wide-spread problems are at a particular home as of the last survey. Of course, the Survey Performance Tool for Nursing Homes cannot substitute for a personal visit when choosing a facility for a family member. Consumers should always be advised to tour a facility and talk with staff, residents and other families before making a deci-

sion. The HEALTH site also offers tips on Choosing a Nursing Home.

Hospitals

Access to current, accurate and meaningful information about hospitals helps health care consumers, purchasers and providers make informed decisions regarding the quality of care. Since 1994, the Joint Commission on Accreditation of Health Organizations (JCAHO) has released performance reports (report cards) measuring nearly 500 standards in health care organizations, such as hospitals, undergoing full accreditation review. HEALTH started collaborating with JCAHO and the Hospital Association of Rhode Island (HARI) in the early fall of 1999 to put performance information about Rhode Island's hospitals on the Internet. In fact, Rhode Island is one of a handful of states piloting a new approach for making JCAHO information more accessible and timely. However, most experts agree that increased access to performance reports is not enough. Judgments about hospitals and other providers should also involve site visits and discussions with personal physicians.

Health Plan Information

The Health Care Accessibility and Quality Assurance Act (Health Plan Act), passed in 1996, requires Health Plans to be certified by the Department of Health, provides due process for health professionals and directs Health Plans to provide information to consumers.

The Health Plan information takes three forms. The "Consumers Guide to Managed Care in Rhode Island" describes how generic, managed care works and defines key terms, such as "medical necessity" and "prospective review." Health Plans distributed more than 500,000 hard copies to members throughout the state. The Internet version, including a Spanish-language edition, is available.

The "Consumer Disclosure" is Health Plan specific and accomplishes two distinct purposes under the law. The first part summarizes the Health Plan's policies concerning confidentiality, anti-discrimination, handling emergencies and other consumer pro-

tections. The second part, called "benefits at a glance," outlines covered services, including whether or not coverage requires pre-authorization, out-of-pocket expenses, limitations and restrictions and additional costs for going out-of-network. It also discusses copays, deductibles and lifetime maximums for each Health Plan.

The Act requires a third part, "ratios and statistics," which reveals the medical loss ratio, proportion of services denied due to adverse determinations, financial/operational measures and other quantitative indicators of Health Plan performance, including HEDIS measures. This section will soon appear on the HEALTH website.

Taken together, these materials give consumers and professionals useful information about quality for some of the key components of the health care systems in Rhode Island. Efforts continue to expand the types and amount of information as well as the kinds of health facilities and professions covered.

HARVARD PILGRIM HEALTH CARE OF NEW ENGLAND (HPHC-NE): INFORMING, EDUCATING AND EMPOWERING THE PUBLIC

Major, unanticipated changes in the health care system provide another opportunity to inform and educate the public using the Internet. When HPHC-NE went out of business at the end of 1999, the fate of more than 155,000 HPHC-NE members, 130 health professionals and more than 1000 other employees hung in the balance.

HEALTH focused on ensuring access, continuity and quality of care during the transition. HEALTH posted on the website a summary of the situation, a toll-free information line, and answers to commonly-asked questions - mostly drawn from HEALTH's Information Line, which operated during the crisis. As events unfolded over the last few weeks of 1999, the website continued to provide updates including: dates of open enrollments; letters to group, non-group and RIteCare (the Medicaid managed care plan) members; names and insur-

ance coverage for providers remaining in Anchor centers; alternative plans for obtaining prescription medications; arrangements for mental health services.

CURRENT AND FUTURE DEVELOPMENT OF THE HEALTH WEBSITE

These few examples illustrate the kinds of information on the HEALTH website and the ways it helps consumers and health professionals. The website also provides information on: the RI Department of Health; health policy and data briefs (such as saving lives by lowering the blood alcohol content for driving while intoxicated and the effect of school-based health centers on drop-out rates); physician advisories (such as on vaccine safety and the incidence of pertussis). It reports research on the efficacy of mammography in Rhode Island. As an added feature, HEALTH's website links to other local and national public health authorities, such as the RI Prevention Coalition and the National Centers for Disease Control and Prevention (CDC). HEALTH plans to continue adding materials to this compendium—expanding the website in both scope and depth.

HEALTH cannot realize the full potential of public health information on the Internet simply by adding more documents. The website must adopt new technologies, such as audio, video and interactive formats. It must remain accessible to people with economic or physical disabilities. Public health must embrace "e-commerce" - enabling customers (citizens, providers, regulated institutions) to obtain products (information, data analysis, licenses) via the web. A key part of that future includes structuring the HEALTH website to meet the needs of physicians and other health care professionals. Only then will it remain a viable tool for realizing "safe and

healthy lives in safe and healthy communities" in Rhode Island.

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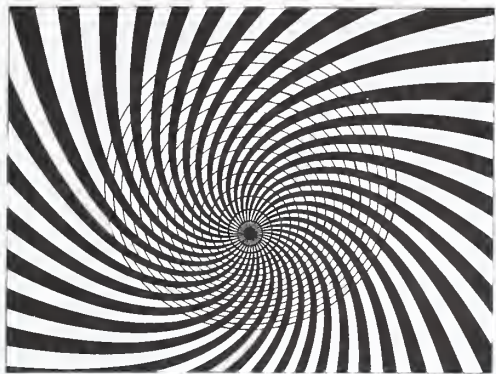
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IMAGES IN MEDICINE

Emphysematous Pyelonephritis

Paolo D. Olcese, MD, and William W. Mayo-Smith, MD

A 45 year-old diabetic male presented to the Emergency Department (ED) with fever, flank pain, and an elevated white blood cell count. A CT of the abdomen performed in the ED demonstrated gas in the left renal collecting system (Figure 1, arrow), a striated pattern of enhancement associated with enlargement of the kidneys (left greater than the right), and perinephric fluid (Figure 2, curved arrow). The patient was admitted and responded to IV antibiotics and was discharged several days after commencement of therapy.

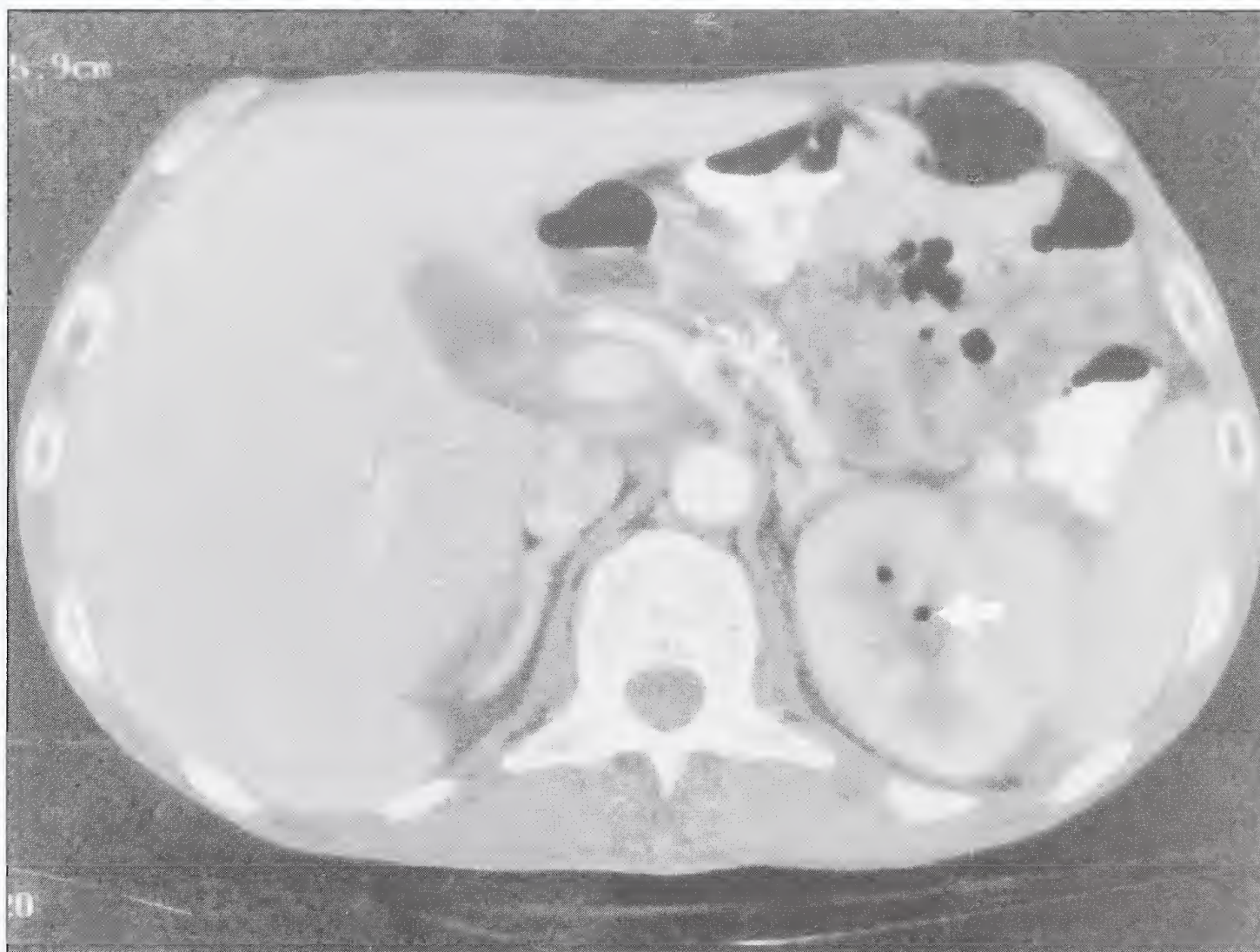
Emphysematous pyelonephritis is a severe, life-threatening infection of the renal parenchyma and perirenal soft tissues. It is associated with gas within the renal parenchyma, collecting system or perinephric soft tissues. The high mortality (7% - 70%) reported in recent literature is due primarily to septic complications. The majority of the bacteria responsible for these infections are the nor-

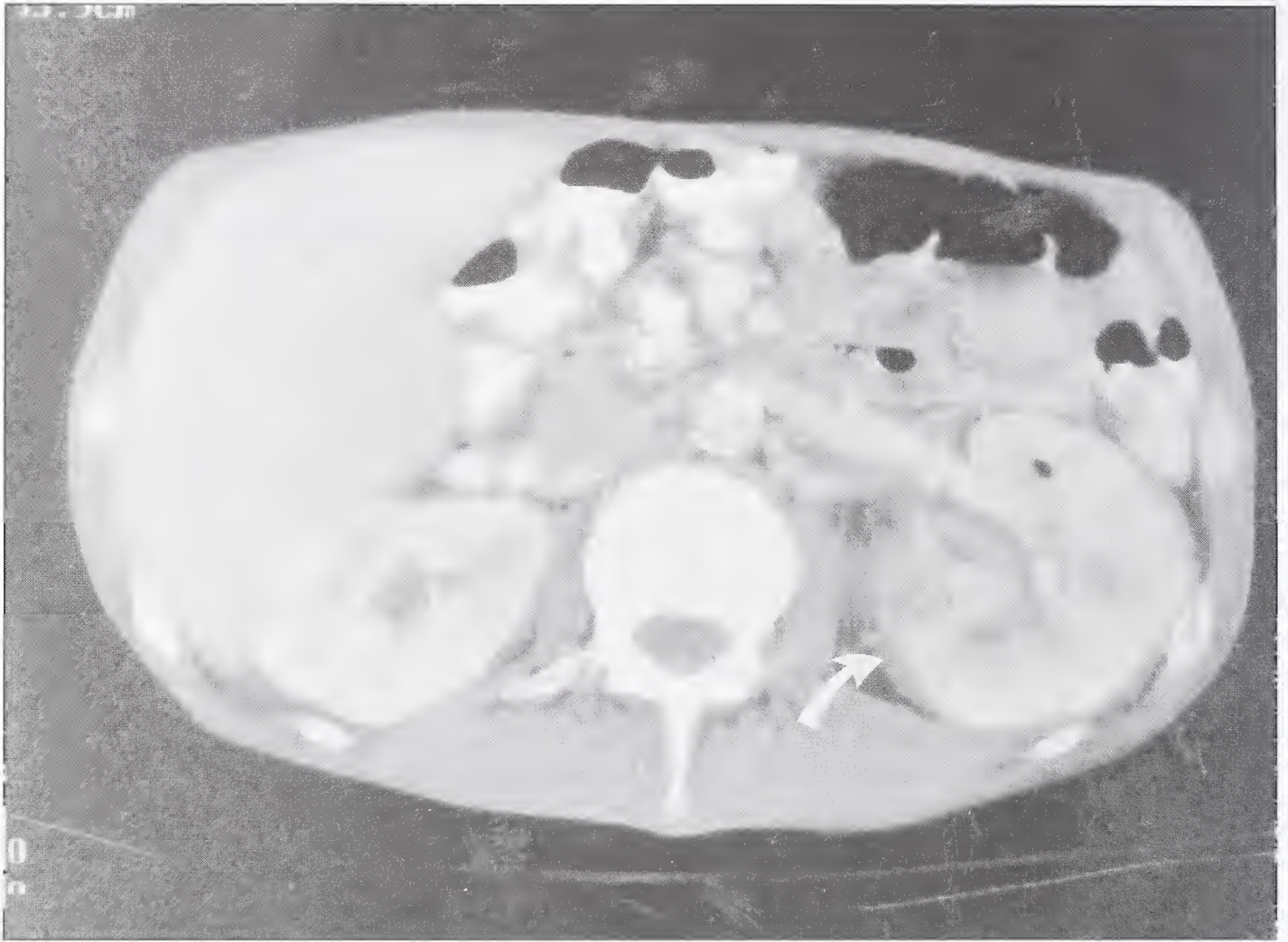
mally encountered urinary pathogens (*E. coli* 68%, *Klebsiella* 9%). Prognosis for patients with emphy-

sematous pyelonephritis varies depending on imaging findings. The presence of perinephric fluid and gas in the collecting system suggests a good immune response and implies a better outcome. Extensive parenchymal destruction, with absence of perinephric fluid and presence of streaky (linear) intraparenchymal gas on CT is associated with a poor prognosis. Characterization with CT therefore remains an important determinant in predicting outcome. Treatment consists of intravenous antibiotics and percutaneous image-guided drainage or nephrectomy depending on the clinical course and severity of infection.

Abbreviations Used:

CT	computed tomography
ED	emergency department





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THE CREATIVE CLINICIAN: CASE OF THE MONTH

"The practice of medicine is an art, not a trade; a calling, not a business ..." – WILLIAM OSLER, Aequanimitas

Editor: Anthony Mega, MD; Co-editor: Fred J. Schiffman, MD

Fulminant Liver Failure Due to Neuroleptic Malignant Syndrome

Sree Hari Kesan, MD, Randy Sid, MD, Daryl Adler, MD, Robert S. Crausman, MD

Neuroleptic Malignant Syndrome (NMS) can be a life-threatening reaction to dopamine receptor blocking drugs, usually antipsychotics. Although often perceived as a rare complication, it has an incidence of about 0.5% per year and often goes unrecognized.¹ Classically, its presentation is characterized by mental status changes, severe muscular rigidity, high temperature and autonomic dysfunction. Increased awareness is important since early recognition and prompt management is associated with improved outcome. The diagnosis, however, presents a challenge since other medical conditions can present with similar symptoms and signs. Further, many patients, particularly early in the course, may not have all the classic features. Here we present a case of a patient with NMS complicated by the extremely rare occurrence of fulminant liver failure.

CASE REPORT

A 43 year-old woman presented to the Emergency Department with worsening tremulousness over the past several days. She complained of alternatively feeling hot and cold. She also noted a productive cough with brown sputum. Her medical history was significant for major depression, anxiety disorder, and an unclear psychotic disorder. Her medications were paroxetine 50 mg po qd, buspirone 20 mg po tid, bupropion 300 mg po qam 150 mg po qhs, trazodone 100 mg to 150 mg po qhs/prn, amantidine 100 mg po tid, quetiapine 50 mg po qam and 100 mg qhs, diphenhydramine 25mg po bid with 50mg qhs, benztropine 1mg po bid. She had an 18-pack/year smoking history and denied any alcohol or drug abuse. Review of systems revealed fatigue, fever, chills, night sweats, headaches, hoarseness, paresthesias, memory loss, hallucinations and insomnia.

In the Emergency Department she had a temperature of 101.4 degrees F, heart rate of 111/min and a blood pressure of 144/67 mm Hg. She had dry mucous membranes and bilateral wheezes as her only somatic abnormalities. She was alert and cooperative but disoriented to the date. She had a mild resting tremor of the hands and no other neurological abnormalities. Tone, in particular, was normal. Blood sodium, chloride, bicarbonate, creatinine and

glucose were normal, as was her urinalysis and chest radiograph. The potassium was 2.8. The complete blood count was normal except for the white blood count of 14,000 with 72% polymorphonuclear cells. The EKG showed sinus tachycardia.

Abbreviations Used:

BP	blood pressure
CK	creatinine kinase
IM	intramuscular
NMS	neuroleptic malignant syndrome

The patient was thought to have acute bronchitis, dehydration and hypokalemia and was treated with nebulisers, intravenous levofloxacin, acetaminophen and intravenous fluids. She defervesced but became mildly agitated, for which she received 2mg of lorazepam intravenously. Minutes later, she became increasingly combative and required 10 people to restrain her. Her behavior escalated despite an additional 4 mg of intravenous lorazepam. Haloperidol 5 mg. was given intravenously, albeit with some reservation, given the consideration of NMS on the differential diagnosis list. Within an hour the patient became obtunded and unresponsive. Her entire body became rigid. Her rectal temperature rose to 108 degrees F and breathing became labored. The first attempt at intubation failed because of the patient's rigidity. Dantrolene 200 mg and diphenhydramine 25 mg were given intravenously before she relaxed enough to permit intubation. Active cooling was begun with a cooling blanket. A decline in her systolic blood pressure to 60 mm Hg. required a dopamine drip, at a rate of 10mcg/kg/min. Six hours later there was a rapid rise in her AST from 23 to 318 and ALT from 41 to 167. She went on to develop fulminant liver failure with an AST of 13,814, ALT of 9,395 and INR of 19.6. The patient died from a brain hemorrhage en route to a hospital where she was to receive a liver transplant. At that point, 72 hours had passed from the time she had been given haloperidol.

DISCUSSION

NMS is an uncommon but potentially fatal idiosyncratic reaction. The mortality was once thought to be around 40%, but much less today, primarily as the result of earlier identification.²

NMS was first described by Delay et al in 1960 during the clinical trials of haloperidol.³ The pathobiology of NMS remains unknown with several hypotheses, none of which explain the entire syndrome, its idiosyncratic occurrence or the panoply of clinical presentations. Sudden and profound central dopaminergic blockade⁴ resulting in a relatively acute dopamine deficiency state is the most favored hypothesis, since a similar syndrome has been reported with dopamine-depleting drugs and in Parkinson's disease patients whose levodopa or amantadine have been suddenly discontinued.⁵

Although NMS typically occurs 3 to 9 days after neuroleptic initiation, it has been known to occur within one hour of the first dose, or as late as several years while on a stable dose.⁶ It normally evolves over a 24 to 72 hour period, but sometimes has a fulminant course.⁷ Alteration of the drug regimen, usually an increase in dose, especially a rapid increase, seems to trigger NMS.⁸ It can affect any age, but has a predilection for young adults and men over women.⁹ Genetic susceptibility remains unproven. Proposed risk factors are long acting (IM) and potent neuroleptics,⁸ physical exhaustion, dehydration, psychomotor agitation, generalized debility, ingestion of intoxicants and a number of psychiatric states including mood disorders, catatonia and schizophrenia.¹⁰ However, the only certain risk factor is the use of a dopamine-blocking drug.

Diagnosis rests on clinical criteria, supportive lab tests, and the exclusion of other potential diagnoses. There is no universally accepted diagnostic criteria. Over the years there

have been many different diagnostic criteria proposed. DSM-IV research criteria require severe rigidity and fever accompanied by 2 of 10 minor features including diaphoresis, dysphagia, tremor, incontinence, altered mentation, mutism, tachycardia, labile or elevated BP, leucocytosis and elevated CPK. Core features of NMS are generally considered hyperthermia, altered consciousness, autonomic dysfunction and muscular rigidity. These features are common to most of the established sets of diagnostic criteria and reported in 95% to 98% of NMS cases (but this varies with the criteria used for diagnosis).^{11,12} In a patient being treated with neuroleptics, when all these core features are present, diagnosis is relatively straight-forward. But most often this is not the case, especially early in the course. Mental status changes or rigidity usually precedes the development of hyperthermia and autonomic disturbances.¹³

The differential diagnosis includes infection, drug withdrawal syndromes, serotonin syndrome, catatonia, malignant hyperthermia and endocrine disorders like thyroid storm and pheochromocytoma. Sepsis should be excluded, as 29% of suspected NMS patients have infections.¹⁴ Fever might exacerbate the extrapyramidal signs that may have been present at baseline. Creatinine kinase (CK) is often considered a marker for NMS. However, CK is increased in 70% of patients taking neuroleptics who are febrile secondary to infections¹⁵ and who don't have NMS.

Management focuses on early recognition and prompt withdrawal of the offending drug, hydration, active cooling

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measures and supportive care. Although drug treatment is debated, most authors recommend prompt use of dopamine agonists.¹⁶ Dantrolene¹⁷ is probably helpful as well and some reports endorse the use of electroconvulsive therapy.¹⁸ Mortality is mainly due to pneumonia or renal failure secondary to myoglobinemia.

We believe this patient had NMS and probably had it as the presenting illness. She had acute bronchitis, but this is unlikely to have induced agitation or confusion. Although quetiapine is an "atypical" antipsychotic that does not cause parkinsonism or acute dystonic reactions, it has been implicated in NMS.¹⁹ We suspect her bronchitis may have precipitated a mild NMS, which was then worsened by the haloperidol. (Interestingly, intravenous haloperidol has fewer extrapyramidal side effects than oral or intramuscular haloperidol.) Physical illness and dehydration is thought to predispose to NMS. Her initial presentation was also compatible with the serotonin syndrome (mental status changes, autonomic instability with myoclonus or tremor), anticholinergic overdose or drug abuse with cocaine or "ecstasy." Enhanced awareness of early signs may provide clinicians the opportunity to recognize incipient cases during the initial hours of onset.

This patient had a fulminant course which made the management difficult. When patients are confused and agitated, haloperidol is a commonly used drug. It is a high potency antidopaminergic agent. In retrospect, this patient who had a paradoxical response to lorazepam should have been given a narcotic, which is reversible.

The occurrence of liver enzyme elevations as high as this is most consistent with severe ischemia, yet there was no evidence of such severe hemodynamic compromise or ischemia elsewhere to support this explanation. Perhaps severe hyperthermia was the primary insult. Hepatic necrosis is known to occur in malignant hyperthermia and heat stroke. Its severity is proportional to maximal temperature reached.²⁰ Dantrolene is known to cause hepatitis and death, but it is usually associated with at least two months of therapy and with high doses (more than 582mg/day).²¹ Liver failure due to NMS is exceedingly rare and its explanation remains elusive.

The challenge for the clinician is to be aware of NMS and its predisposing factors, to recognize it early and to initiate treatment so that lethal complications are prevented.

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Treatment of Atrial Fibrillation with Warfarin in Rhode Island

David R. Gifford MD, MPH, and Laura R. Silverman

Atrial fibrillation is the most common chronic cardiac arrhythmia, affecting about 2 million people in the United States.¹ It is a significant risk factor for stroke, particularly as patients age, and if other risk factors - hypertension, diabetes mellitus, heart failure, or previous stroke/TIA - are present.² Atrial fibrillation is particularly common in the elderly. In 1996, approximately 70% of people with atrial fibrillation were between 65 and 85 years old.¹

In 1998, the National Stroke Association reviewed 46 stroke prevention guidelines and consensus statements from sources including the American College of Chest Physicians, the American Heart Association and the American Academy of Neurology.³ From this review the National Stroke Association published a consensus statement recommending the use of warfarin anticoagulation for patients with atrial fibrillation who are 75 years and older, regardless of whether or not other risk factors are present, and for patients 65-75 years old who have any other risk factor. For patients 65-75 years old without any other risk factor, warfarin or aspirin is recommended, and aspirin for those under 65, who are at a very low risk for stroke. The use of warfarin in these populations can significantly decrease the risk of stroke and the benefits greatly outweigh the risk of a major hemorrhage.⁴

HCFA has chosen stroke prevention as a national focus for the Peer Review Organizations' (PRO) current efforts. The overall goal is to reduce the incidence of preventable strokes in patients diagnosed with atrial fibrillation by increasing the use of warfarin in eligible patients and assuring that patients receive discharge planning and education about warfarin monitoring.

As a precursor to the current national HCFA project, Rhode Island Quality Partners, Inc. (RIQP) participated in the Kerr L. White Institute Stroke Prevention Project (KWISP). The goal was to improve the prevention of strokes in patients with atrial fibrillation by increasing the proportion of patients with atrial fibrillation on warfarin; increasing the proportion of patients with atrial fibrillation who are prescribed warfarin upon hospital discharge; increasing patient education regarding anticoagulation and follow-up monitoring of anticoagulation after hospital discharge.

Abbreviations Used:

HCFA	Health Care Financing Administration
INR	international normalized ratio
KWISP	Kerr L. White Institute Stroke Prevention Project
PRO	Peer Review Organization
RIQP	Rhode Island Quality Partners
TIA	transient ischemic attack

Data were collected from medical records in three Rhode Island hospitals for all Medicare discharges with any ICD-9 code for atrial fibrillation between May 1 and October 31, 1996 and again between March 1 and August 31, 1998. Based upon data collected during 1996, hospitals developed quality improvement programs. The effectiveness of these programs were evaluated by collecting the same data again in 1998.

In Rhode Island approximately half of all patients with atrial fibrillation at admission who did not have a contraindication for anticoagulation were being treated with warfarin (Table 1). This did not change during the course of the project. Physicians rarely provided a documented ratio-

Table 1.
Comparison of baseline versus follow-up data on management of Atrial Fibrillation

Measures	1996 Data	1998 Data
Warfarin at admission	51%	49%
Documented rationale for not using warfarin	9%	13%
INR therapeutic at admission	27%	43%*
Warfarin at discharge	60%	58%
Patient education about warfarin	25%	53%*
Planned follow-up INR	31%	63%*

*p>0.05

nale for not providing warfarin anticoagulation. However, a significantly greater proportion of patients was admitted with a therapeutic INR at the end of the project. At discharge nearly 10% more of the patients were started on warfarin (Table 1). Education about warfarin and plans for INR monitoring following hospital discharge significantly improved during the course of the project, however, there was still room for further improvement.

This data suggest that nearly a third of patients in Rhode Island with atrial fibrillation are not receiving warfarin. A recent meta-analysis suggests that for patients with an average stroke risk from atrial fibrillation, warfarin will prevent 30 strokes at the expense of 6 major bleeding episodes.⁴ When compared to aspirin, warfarin was more effective in all patient populations but the difference was less for low risk patients - those with younger age and no additional risk factors. Physicians should discuss the risks and benefits of warfarin with their patients who have atrial fibrillation and strongly encourage those who are older and have additional risk factors to start on warfarin.

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The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.

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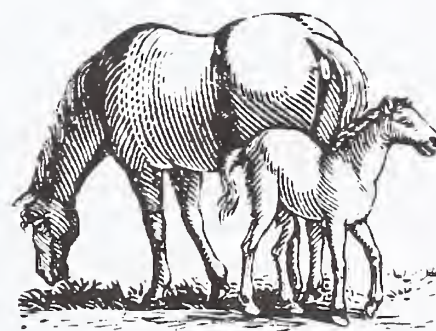
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The Physician's Role in Public Health Statistics and Surveillance

Jay S. Buechner, PhD

For over ten years, the Rhode Island Department of Health (HEALTH) has sponsored the monthly submission of Health by Numbers to *Medicine & Health/Rhode Island*. The principal reason for this collaboration has been to offer physicians a statewide perspective of the health status of the population and the characteristics of the health care system. A second reason has been to demonstrate to physicians the capacity of HEALTH's data systems to produce statistical measures and surveillance indicators for the state's population and health care system. Both purposes are intended to support physicians in their roles as practitioners, researchers, teachers, and administrators.

Another, less explicit, purpose of Health by Numbers is of great importance to the operation of the HEALTH statistical and surveillance function. Physicians are a primary source of the information held in many of the data systems that produce health status indicators and health care statistics for the state. For some data systems, physicians themselves record and submit the data items that are entered; in others, information placed in the medical record by physicians is abstracted and entered. In both cases, the accuracy, completeness, and timeliness of the data depend on what physicians do. Health by Numbers can demonstrate the use of these data systems and provide a "feedback loop" to physicians for the data that originate with them either directly or indirectly.

As part of the "feedback loop," this report presents a brief description of physicians' roles as data sources for the key databases that support the HEALTH statistical and surveillance function.

Methods

Although the Department of Health maintains over 200 databases relating to various public health programs and functions, a subset of 30 databases have been identified as most useful for supporting the production of statewide health statistics and health surveillance indicators.¹ For this report, these databases were organized into seven categories. (Table 1) The seven categories and their descriptions are as follows:

Abbreviations Used:

HEALTH	Rhode Island Department of Health
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Vital records - databases consisting of registered vital events (births, deaths, and fetal deaths) and derivative databases, e.g., occupational deaths

Reportable conditions - diseases or injuries reportable under state regulation, including certain infectious diseases, newly diagnosed cancers, traumatic brain injuries, etc.

Health care utilization - health care encounters with certain health providers, such as inpatient hospitalizations or emergency medical service responses

Licensure - information on health care facilities and professionals licensed to operate in the state

Health surveys - information collected directly from samples or subsets of the population concerning health status, health behaviors, health care coverage, etc.,

Program management information systems - data collected in the course of providing public health services or benefits to a relatively large segment of the population

Composite - information systems combining more than one of the above types of data

The physician's role in each database was characterized as either (1) direct reporting, (2) reporting through the medical record, (3) both roles, or (4) neither role. These characterizations were summarized according to the database categories above.



Table 1.
HEALTH statistical and surveillance
databases, by category

Vital Records

Birth Records
Census of Fatal Occupational Injuries
Death Records
Fetal Death Records
Infant Mortality and Linked Birth-Infant Death
Records

Reportable Conditions

Cancer Registry
HIV/AIDS Reporting System
National Electronic Telecommunications System
for Surveillance
Sexually Transmitted Diseases Surveillance
Traumatic Brain Injury Surveillance
Tuberculosis Surveillance

Health Care Utilization

Cardiac Services Registry
Emergency Medical Services Ambulance Run
Reports
Health Center and Provider Office Immunization
Assessments
Home Visiting Data
Hospital Discharge Data
Hospital Financial Dataset
Lead Screening Data
Minimum Data Set for Nursing Home Care
School Immunization Survey
Universal Newborn Screening

Licensure

Health Facility File
License 2000

Health Surveys

Adolescent Substance Abuse Survey
Behavioral Risk Factor Surveillance System
Health Interview Survey
Youth Risk Behavior Survey

Program Management Information Systems (MIS)

Early Intervention Program
Women, Infant, and Children (WIC) Food
Supplement Program

Composite

Maternal and Child Health Data

Table 2.
Physicians' roles in providing data to
HEALTH statistical and surveillance
databases, by category

Database Category	Physicians' Role			
	Direct Only	Medical Record Only	Both Methods	Neither Method
Vital Records	1	0	4	0
Reportable Conditions	3	1	2	0
Health Care Utilization	0	5	0	5
Licensure	1	0	0	1
Health Surveys	0	0	0	4
Program MIS	0	2	0	0
Composite	0	0	1	0
Total	5	8	7	10

For four categories of databases - vital records, reportable conditions, program management information systems, and composite - physicians served as reporters for all databases. For only one category, health surveys, were physicians not at all involved as a data source. In each of the two remaining categories - health care utilization and licensure - physicians were key reporters for half of the included databases.

Discussion

Overall, physicians are the most prolific contributors of the information that supports program operations and policy development in public health. In half of the 30 most used databases, the physician provides information through a medical record and may not be aware of his or her role as a data source. As important contributors, physicians should be aware of their roles as data sources and informed of the uses to which these data are put. As important data users, physicians should be aware as well of the opportunity to access HEALTH data to support their professional activities, including medical practice, research, teaching, and administration.

Ultimately, the quality and completeness of the information supplied by physicians impacts on the usefulness of the databases to support public health decision-making. The regular publication of analyzed health data through Health by Numbers provides physicians an opportunity to examine the fruits of their labors, as well as giving them a source of information on health status and health care in Rhode Island.

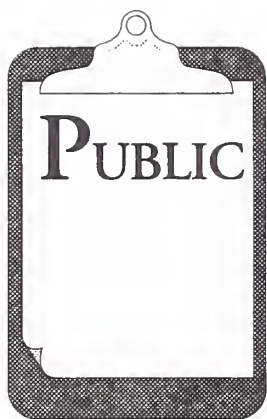
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Results

Physicians are key reporters for 20 of the 30 specified HEALTH statistical and surveillance databases. (Table 2) In a total of 12 databases, physicians served as direct reporters; in a total of 15 databases, physicians were data sources through medical records. (For seven databases, physicians contributed in both ways; these were included in both totals.)



PUBLIC HEALTH BRIEFING

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by John P. Fulton, PhD

West Nile Virus Surveillance and Prevention

Thomas Bertrand, MPH, and Utpala Bandy, MD, MPH

The introduction of West Nile virus (WNV) in the northeastern United States during the summer and fall of 1999 has prompted public health and environmental management officials in Rhode Island to coordinate state-wide surveillance and prevention activities. These activities are intended to reduce mosquito-breeding habitats, to promote personal protection from mosquito bites, and to monitor WNV activity in humans, mosquitoes, and birds.

WEST NILE VIRUS

WNV is a mosquito-transmitted disease that can cause encephalitis. It is common in parts of Africa, western Asia, and the Middle East. It appeared in the New York City region in the summer and fall of 1999, where 59 cases (including 7 deaths) occurred. This was the first incidence of WNV recorded in the Western Hemisphere.

The natural cycle of WNV involves birds and mosquitoes. Mosquitoes acquire the virus from biting infected birds. The mosquitoes may then transmit the infection to birds, horses or humans. Some bird species display no symptoms, while others may get sick and die. There is no evidence that people can contract WNV directly from either live or dead birds. Birds migrating northward in the spring are considered the most likely source of introduction of the virus to the northeast. WNV can survive in overwintering mosquitoes. In March, 2000, WNV was detected in mosquito RNA retrieved from pools in Queens, New York, and in the remains of a red-tailed hawk that died in Westchester, New York.

Several species of mosquitoes in Rhode Island can transmit WNV from birds to humans. The urban "house mosquito" readily bites both birds and humans. This species is suspected to be most responsible for the 1999 outbreak in New York City. Other common species that can transmit WNV include one found throughout wooded areas of Rhode Island and two that are found in saltmarshes.

Most infections due to WNV are mild. Symptoms include fever, headache, and body aches, often with skin rash and swollen lymph glands. More severe infection may be marked by headache, high fever, neck, stiffness, stupor, disorientation, coma, tremors, convulsions, muscle weakness, paralysis, and rarely, death.

Abbreviations Used:

HEALTH	Rhode Island Department of Health
IV	intravenous
RIDEM	Rhode Island Department of Environmental Management
WNV	West Nile virus

There is no vaccine to protect individuals for WNV. No specific therapy is available for treatment of infected individuals. In more severe cases, intensive supportive therapy is indicated, i.e., hospitalization, intravenous (IV) fluids and nutrition, airway management, ventilatory support (ventilator) if needed, prevention of secondary infections (pneumonia, urinary tract, etc.), and good nursing care.

SURVEILLANCE

Because it is unknown whether the virus can persist over the winter, whether it has already or will spread to new geographic locations, and what the public health and animal health implications of this introduction may be, the need was recognized to develop laboratory-based surveillance and prevention and control programs to limit the impact of the virus. In accordance with guidelines developed by the Centers for Disease Control and Prevention and the U.S. Department of Agriculture, Rhode Island, along with areas from Massachusetts to Texas along the Atlantic and Gulf coasts, is preparing for the possible emergence of WNV in the spring or summer of 2000. Three surveillance activities have been established:

Active bird surveillance. The Rhode Island Department of Environmental Management (RIDEM) is coordinating with veterinarians and animal control officers to retrieve dead birds and submit the specimens to the Rhode Island Department of Health (HEALTH) Laboratory for processing the University of Rhode Island for molecular analysis. RIDEM is also visiting five crow rookeries on a weekly basis to inspect for dead crows.

Active mosquito surveillance. RIDEM is monitoring mosquito populations to detect WNV and other arbovirus virus activity, to help identify potential mosquito vectors and to monitor population densities of those vectors. Mosquito pools at 24 sites throughout Rhode Island are sampled weekly for testing at the University of Rhode Island.

Enhanced passive human surveillance. As a backup system to detect the presence of WNV activity, passive surveillance enhanced by general alerts to health care providers are being conducted for cases of viral encephalitis.

PREVENTION EFFORTS

The risk of people acquiring WNV will be minimized by communities' efforts to reduce mosquito populations. The best approach is to target larvae (the immature aquatic stage) before they become adults. This strategy is preferred because larvae are concentrated and may be targeted with environmentally friendly products. Appropriate habitats for larval control include stormwater catchment basins, roadside ditches, and retention ponds. Tire piles and other large sources of stagnant water should be eliminated. RIDEM is partnering with public works officials in cities and towns throughout Rhode Island to control mosquitoes through larval source reduction.

A critical component of the prevention program is public education about WNV and other arboviruses, how they are transmitted, and how to prevent or reduce risk of

exposure. The cornerstone of public education is a partnership with the media to inform people about WNV without causing alarm. Officials from HEALTH and RIDEM have met with media representatives to enlist their assistance with this effort. Other public education activities include the distribution of WNV easy-to-read pamphlets and the posting of WNV information on government web sites.

PHYSICIAN REMINDER

Physicians are reminded that recognition or strong suspicion of arboviral encephalitis is to be immediately reported to HEALTH by telephone (weekdays: 401-222-2577, afterhours/weekends: 401-272-5952). Laboratory testing is not necessary prior to filing a report. Additional clinical information about WNV can be found on the HEALTH web-site <http://www.health.state.ri.us>.

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BOOK REVIEWS

Guide To Clinical Preventive Services, 2nd Edition

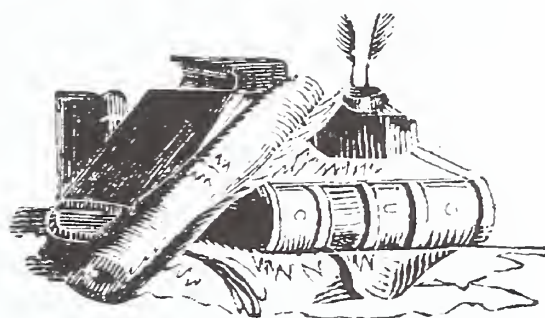
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Reviewed by Sharon L. Marable, MD, MPH

The Guide to Clinical Preventive Services is a reference book on the effectiveness of services such as screening tests, patient education & counseling and immunizations. The second edition of the *Guide*, published in 1997, is an updated version of the original 1989 report of the predominately physician United States Preventive Services Task Force (USPSTF). This latest volume represents the Task Force's critical review of the scientific literature on many preventive interventions, with the Task Force's final recommendation of a test, immunization or counseling intervention only after the Task Force determined that the preventive service is effective based on published clinical research.

The Guide analyzes the scientific evidence for and against over seventy preventive health interventions which include counseling patients on tobacco use, sexually transmitted diseases and unintentional injuries. The Task Force also provides its conclusions on recommended immunizations as well as chemoprophylaxis with aspirin or hormones. Moreover, similar to the first edition, the report includes age-specific charts listing recommended preventive services for patients in various age groups,



Abbreviations Used:

USPSTF United States Preventive Services Task Force

which primary care physicians may find beneficial.

The chapter discussions of each topic are formatted in terms of: 1) the burden of suffering in the United States from the disease 2) assessment of the accuracy of the screening test for a specific disease 3) efficacy of early detection, behavioral risk reduction, chemoprophylaxis, or immunization for a specific condition 4) discussion and the final USPSTF recommendation. Although the final conclusions in this *Guide* are those of the Task Force, each chapter also includes a section with the recommendations from medical societies such as the American College of Obstetricians and Gynecologists, American Academy of Pediatrics, American Academy of Family Physicians, American College of Physicians and the American College of Cardiology. This additional perspective is particularly useful in chapters where the Task Force found insufficient clinical research data to recommend for or against a certain clinical preventive service. Approximately one hundred references are provided at the end of each chapter.

The United States Preventive Services Task Force announced important findings from their extensive review process. First, the Task Force determined that many of the health care problems we see in the office are now more often the consequence of

the lifestyle choices made by our individual patients. The Task Force emphasized that the leading causes of death in the United States, like cancer, cardiovascular disease, cerebrovascular disease, injuries and human immunodeficiency virus infection, are linked to a small number of behaviors which include smoking, physical inactivity, substance abuse, poor dietary choices and failure to use seatbelts. Therefore, the Task Force urges all clinicians to seize every opportunity to deliver a preventive service or message to a patient. Consequently, this updated *Guide* lists patient education strategies and counseling techniques the provider can incorporate in practice to help patients change behavior. The Task Force recognized physicians are struggling with providing patients consistent office-based health education and counseling due to reimbursement issues, lack of human resources and lack of time, and the Task Force did not have the authority to address the solutions to these complex issues in the body of this report. However, the Task Force referred the reader to "Put Prevention into Practice" program administered by the Agency for Healthcare Research and Quality (www.ahrq.gov) and the Clinician's Handbook of Preventive Services, for guidance on ways to implement these guidelines. Second, the Task Force concluded that for some health problems, community-based interventions may produce better results than solely delivering the preventive service to an individual in a clinical health care setting. As a result, the government recently commissioned a Task Force on Community Preventive Services, which will develop evidence-based recommendations for preventive services administered within the community. The United States Preventive Services Task Force encourages all clinicians to come involved in community health initiatives and participate in the development of public health policy.

The *Guide* has the limitations of any document based on a review of clinical research. For instance, the USPSTF studied those preventive services performed on asymptomatic persons in clinical venues. Therefore, the Task Force's recommendations do not apply to preventive interventions provided outside of the clinical setting, such as a community health fair or to individuals who already have clinical manifestations of the target conditions. Moreover, the recommendations focus on the performance of certain preventive services were based upon the quality of the supporting scientific evidence at the time of publication.

Although this *Guide* was developed specifically for primary care clinicians, physicians with an interest in prevention or evidence-based medicine will also find it to be an essential desk top reference.

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Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report

Provisional Occurrence Data
from the
Division of Vital Records

Underlying Cause of Death	Reporting Period			
	May 1999	12 Months Ending with May 1999		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	216	3,015	305.0	3,545.5
Malignant Neoplasms	200	2,462	249.1	6,606.5
Cerebrovascular Diseases	39	567	57.4	773.5
Injuries (Accident/Suicide/Homicide)	28	374	37.8	7,220.0
COPD	39	495	50.1	465.0

Vital Events	Reporting Period		
	Novem. 1999	12 Months Ending with November 1999	
	Number	Number	Rates
Live Births	922	13,160	13.3*
Deaths	744	9,801	9.9*
Infant Deaths	(6)	(92)	7.0#
Neonatal deaths	(6)	(70)	5.3#
Marriages	466	7,728	7.8*
Divorces	277	2,807	2.8*
Induced Terminations	334	4,868	369.9#
Spontaneous Fetal Deaths	89	1,162	88.3#
Under 20 weeks gestation	(84)	(1,090)	82.8#
20+ weeks gestation	(5)	(72)	5.5#

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 988,480

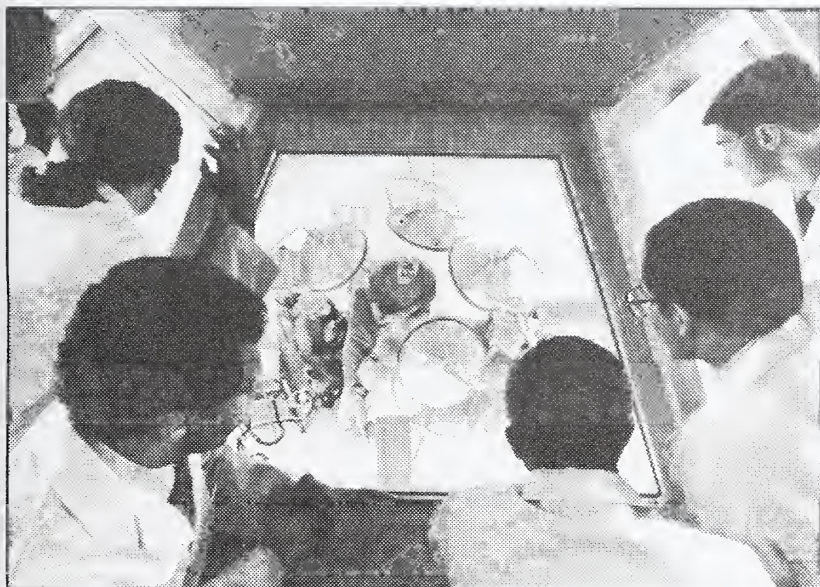
(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population # Rates per 1,000 live births

Corrections to *Vital Statistics*, printed April 2000. For the 12 months ending with October 1999, the rate of live births was 13.6, not 13.5; and the number of spontaneous fetal deaths 1,148, not 1,149.

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THE RHODE ISLAND MEDICAL JOURNAL

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NINETY YEARS AGO

[MAY, 1910]

Throughout his 25-year career, J.H. Davenport, MD, had collected the literary works of physicians ("No men owe it to themselves to take their recreation regularly and persistently more than physicians....Each one of us should have... some hobby.") In "The Contributions of Medical Men to General Literature," he described the highlights of his 1000-volume library: "There seems to be no country that has not furnished at least one example of a physician becoming eminent for literary work, usually, however at the expense of his medical work." He had collected works by Schiller (Germany), Rabelais and Eugene Sue (France), Michael Servetus (Spain), John Keats (England). American physician-authors included Dr. David Ramsay, a surgeon in the Army of the Revolution, who wrote historical treatises, and the contemporary Dr. S. Weir Mitchell, a neurologist and authority on prisons, who, in addition to 125 scholarly papers, wrote 5 volumes of poetry, 13 novels (e.g., *The Autobiography of a Quack*, *When All the Woods are Green*), and a volume of essays (*Doctor and Patient*).

F. Williams, MD, in "Tuberculosis in Children," drew from the observations of 125 children, ages from infancy through 15, seen in the outpatient department at Rhode Island Hospital in 1909. "A great deal has been accomplished already in controlling the disease, but what has been done has for the most part been for adults..." He cited key factors: the presence of tuberculosis in the home (when a sick person cared for a child), poor food, lack of ventilation, and, perhaps, nose and throat abnormalities. Calling for "fresh air schools," Dr. Williams considered other options ("either the consumptive at home must be removed or the child should be removed") as "out of the question."

G.W. Van Benschoten, MD, in "The Manifestations of Syphilis in the Eye," noted that all parts of the eye were susceptible. For transmission to the eyelids and conjunctiva, he cited several modes of infection, including kissing, coughing, and removing foreign bodies from the eye by licking (a practice "common in Russian towns.")

FIFTY YEARS AGO

[MAY, 1950]

In "Diagnosis of a Case of Uterine Malformation with Kidney Agenesis," Harold Libby, MD, noted that most cases of uterine malformation remained undiscovered, until a complication arose. In this case - a 19 year-old newly-wed who complained of a menstrual episode with passage of retained discharge - the physician had two clues. First, at age 14, the patient, who had been having irregular periods for a year, suddenly and profusely started to menstruate in school. In the hospital, physicians found that she possessed only one kidney. After discharge, she returned to school and was fine. Second, three years

later, her mother, now pregnant, miscarried with a 5 1/2 month fetus that had hereditary agenesis of the extremities.

A. M. Phillips, MD, and W.A. Leonard, MD, in "Thalassemia Minor - A Report of Ten Cases," cited a Rochester, New York, survey of persons of Italian descent: 1 case of Thalassemia Major for every 2368 births, 1 case of Thalassemia Minor for every 25 births.

An editorial on "Malpractice" argued against a state proposal to allow statements in medical books to be admitted as evidence in court, since the authors would not have been available for cross-examination.

Joseph Smith, MD, Superintendent of Health, shared statistical good news. The year 1949 marked a record low in the number of deaths: the fewest (3058) since 1898 (2928). There was a slight increase in deaths from heart disease, but a slight decrease in deaths from nephritis, cerebral hemorrhage, and cancer. In 1949 the fewest number of people died from pneumonia in any one year since the Civil War. Although the state had 3254 cases of measles, only two people died from it. And the infant mortality rate was the lowest ever recorded in Rhode Island.

TWENTY FIVE YEARS AGO

[MAY, 1975]

This issue focused on Brown's reborn medical school.

In "Traditions," Horace Martin, PhD, reminded readers that between 1816 and 1828 Brown had graduated 95 medical doctors. He elaborated on the history of medical education, describing the medieval schools in Bologna, Montpellier and Paris.

Anthony Caldamone described "The Flexible Curriculum at Work," noting the variety of electives students in the first medical class had selected.

Peter LeWitt profiled "The Class of 1975: A Differential Diagnosis." He suggested, "The prognosis is probably in the direction of primary health care, specialized or general." Demographically, 23% of the class were women - "one of the highest percentages in the nation's graduating classes this year." Brown had no minority students in the class, "although affirmative action policies have long been a part of admission policies." Almost half (45%) of students planned to stay in Rhode Island, although "very few" were natives - "much to the dismay of local politicians." Individual pictures of the students, with write-ups, followed.

Arthur Horwich and Pardon Kenney presented "Case Records of the Brown University Medical School: Early Clinicopathological Exercises." A 24 year-old medical student had been found "wandering about the East Side babbling neuropathological trivia." The report continued: "The patient had been well until seven years earlier when he entered the Brown Program in Medicine. Fatigue was noted initially, related to all-night study of Bacchus with local barmaids. Classroom narcolepsy soon followed, and a local university health service prescribed vitamin E and abstinence of all sorts." The treatment was "obvious": "immediate conferral of the MD [degree]."



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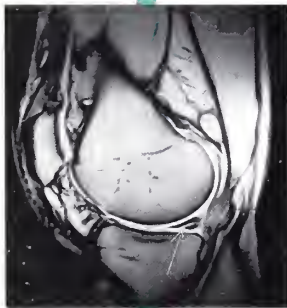
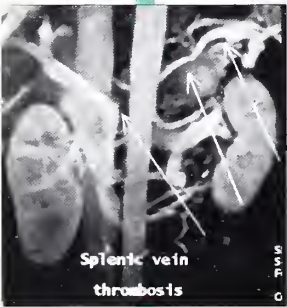
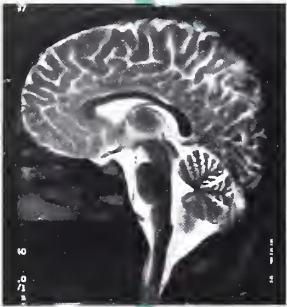


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The Academic – Corporate Interface in Medicine

Like Caesar's wife, academic physicians are supposed to be above suspicion. (If only this were true!) As our health industry continues to collapse, academically-based clinicians, researchers and educators are as beset by financial problems as are private practitioners and hospitals. The face of academic medicine has changed and continues to change. As financial restraints progress, the enlarging presence of private industry and its influence increases, jeopardizing some of the foundations of the academic enterprise.

There is no free lunch. Drug representatives routinely provide "free lunch," free theater tickets, pens, pads and what-nots to physicians. They've done this forever and obviously think it buys them something or the practice would stop. This occurs in private as well as academic offices. The academic physicians tend to specialize more and therefore attract greater attention, but from fewer drug representatives.

Sponsored talks. My department has weekly grand rounds but no budget. No money is provided to bring in speakers to educate us and keep us up to date. We depend therefore on local experts within the Brown community, local private practitioners and occasional experts from Boston to "volunteer." In addition we use drug company "donations" to underwrite

guests from further afield. Current regulations require these donations to be laundered through the institution. This allegedly guarantees the unfettered nature of the lecture. I believe that a talk critical of the sponsor's product leads to the speaker never being sponsored again. So the talk is "unrestricted," but the speaker knows he will never get invited anywhere again on that company's dime if the message isn't good. The choice of the topic is not always free either (although it sometimes is), depending on the company. Can we tolerate these infringements? I think so. Does this alter the speaker's message? I believe not. The process selects for speakers who like to talk about drugs, and have had positive experiences with the sponsor's product, leading to a "natural," mutually beneficial partnership. Does this process lessen our chances of hearing another point of view? The answer is a qualified yes. Let me give myself as an example. In recent years I have focused on the effects of atypical antipsychotic agents in Parkinson's disease. I think well of two drugs, not so well of a third and denounce the use of the fourth. Clearly only the first two drug makers want me to speak. At all my talks I will give my opinion, tempered by different experiences reported by some others, but I express my own beliefs. One worries that the loudest messages

get heard best.

Clinical research, academic publications, private consulting. Clinical trials and studies that demonstrate drug efficacy and safety are increasingly important revenue streams for physicians in pri-



ate practice as well as academics. Private companies devoted entirely to clinical trials have developed. These exist purely for profit and may have fewer quality controls than an expert's own practice. (I received a call from a urologist asking if I would like to participate in a headache medication trial. I deferred, as my neurological specialty is Parkinson's disease. The urologist's response: "I guess I'll do it myself.")

Are academic specialists better suited to performing these studies? It depends on the level of expertise required for the study. Presumably a neurologist would provide higher quality for a headache study than a urologist but a good neurologist in practice might be readily interchangeable with one who is hospital-based.

Should academics, who design the clinical trials and who receive personal income from consulting for a company, be involved in testing their drugs or in writing articles for medical journals that review these drugs? Double-blind, placebo-controlled randomized drug trials are designed to reduce bias as much as possible. One would assume that the best studies are designed by the physicians with the greatest skill in clinical design as well as in treating the illness under evaluation. In most cases such experts are medical school-based faculty. Since most drug advances have derived from corporate research, it would be counter-productive to deny the use of the university-based experts. The real question then is how to prevent their corruption from the corrosive influence of money. One mechanism is to channel all private funds through the university or a particular department. Some research consortiums require this, for the clearly



stated purpose of preserving confidence in the lack of bias in the investigator/consultant. There is a certain disingenuousness to this, however, since this income either produces a significant benefit to the researcher or, finding no gain in this extra-curricular work, the researcher gives it up. The expert who publishes articles is ethically required to review and interpret data, dispassionately and honestly, whether or not to the benefit of an involved company and should also provide honest opin-

ions. Whether these opinions and reviews are in fact unbiased may be difficult to determine. Requiring the author to publish all financial ties allows the reader to reach a conclusion about the accuracy of the interpretation.

How far this corporate-academic relationship should go is a major issue. Departments that increasingly depend on corporate sponsorship are, on the one hand, putting themselves at risk for compromising their intellectual

honesty, but also broadening their financial foundations in order to survive in an increasingly underfunded, hostile environment.

— Joseph H. Friedman, MD

The author is active as a paid speaker, consultant and investigator for pharmaceutical companies.

Opposing points of view are encouraged.

Evil Shall Not Enter This House

The third book of the Bible, called Leviticus, provided the ancient Hebrews with an instructional manual during their years of wandering. Some of these guidelines pertained to ways of maintaining the health and integrity of this nomadic community: proscribed foods, distinctions between clean and unclean things, and preventive health measures. In Chapter 13, comes a statement concerning individuals with certain diseases [called *tsara'at*, a complex of ailments loosely translated as leprosy.] "Being unclean he shall dwell apart; his dwelling shall be outside the camp." The indicted person, when eventually found free of disease, was then allowed to return.

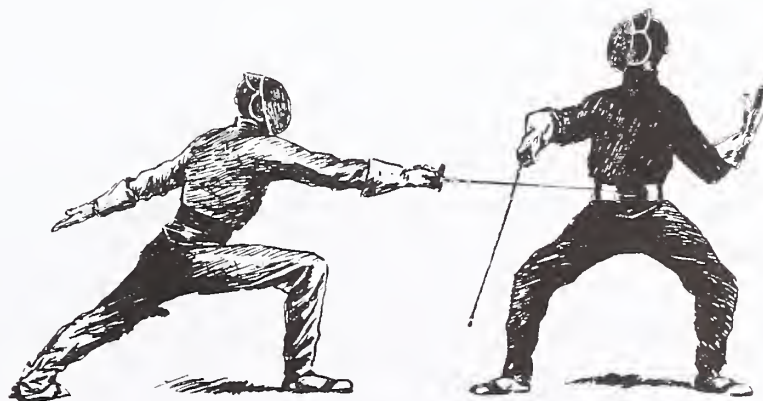
To understand this uncompromising action, four assumptions are made: First, that these nomadic Hebrews believed that certain diseases could be passed from afflicted to unafflicted solely by touch or by close proximity; second, that isolating a person with the disease will diminish the likelihood of contagious spread to the larger community; third, that contagiousness in the afflicted does not go on indefinitely but may abate with time; and fourth, that there is a moral basis for placing the welfare of the many over the liberty of the few.

Forceably detaining persons with alleged contagions was commonplace in many cultures but it was not until the bubonic plague epidemic in 14th Century Europe that a restrictive policy was formalized and isolation procedures widely undertaken. Since plague generally entered countries through their seaports, seafaring nations detained arriving vessels for extended intervals. The presumption was made that a shipboard pestilence, if present, would burn itself out during the weeks of detention. Adriatic ports such as Venice designated small offshore islands [called lazarets, named after the Biblical character Lazarus who had suffered from leprosy] where incoming ships were required to wait for 40 days until clearance was granted. This practice was called quarantine, from the Italian word *quaranta*, meaning forty. In medieval law, quarantine also designated the 40 days during which the widow may remain in her recently-deceased husband's home.

Why 40 days? The number 40 is frequently mentioned in the Scriptures as a symbolic interval of fulfillment [the duration of the flood, Moses' 40 days on Mt. Sinai, King David's regal tenure, Christ's 40 days of temptation in a Judean wilderness site called Quarantania.]

By the 19th Century, every maritime nation had its own body of quarantine legislation and its own list of diseases warranting exclusion. To enter the United States at the beginning of the 20th Century, for example, an immigrant had to be visibly free of tuberculosis, trachoma, venereal diseases and a number of specified communicable diseases. By international consensus, a yellow flag [called yellow-jack] when flying from a ship's mast signified either pestilence aboard or that the ship was in quarantine custody.

International commerce increased so dramatically during the 19th Century that nations began to view quarantine as an impediment to trade. Furthermore, when commerce had been conducted by sailing vessels, the transit time between ports was often measured in weeks or months; and an epidemic illness aboard ship would surely have made itself evident before landfall. But as steam-powered vessels replaced sailing ships, the interval between ports was reduced to days. Thus, for example, a person who recently contracted smallpox [with an incubation period of about 14 days] might embark in England and land ten days later in New York without showing evidence of the disease until he was days beyond the quarantine station.



A British commission studying the feasibility of quarantine stated: "If it [quarantine] works, it is valuable beyond price; if it cannot, it is a barbarous encumbrance, interrupting commerce, obstructing international intercourse, periling life, and wasting large sums of public money." Great Britain's General Board of Health, in its 1849 report to Parliament, declared quarantines and sanitary cordons to be signal failures particularly since diseases such as yellow fever and cholera did not seem to be communicated by touch, as with smallpox.

The Board noted that cholera had arrived in Great Britain despite stringent quarantine. Furthermore they observed that none of the nurses or physicians tending the many cholera victims contracted the disease. Nor could they explain the mysterious paths taken by cholera in its spread through the cities of Britain. "Great epidemics," declared the Board, "are governed by laws over which quarantine can exercise no control."

The German city of Hamburg was the site of a devastating cholera epidemic in 1832. Ten years later, Hamburg experienced a terrible fire reducing much of the city to ashes. The city was rebuilt according to strict sanitary precepts; and when cholera returned, it avoided the reconstructed region. The Board therefore blamed cholera upon deplorably filthy living conditions. They concluded: "Quarantine pays no regard to these conditions. Blindly intent on accomplishing an impossible object, it overlooks the circumstances on which the existence and extension of the

disease really depend." The true protection against pestilential disease, they declared, was not quarantine regulation but sanitary measures. Quarantining had neither scientific nor humanitarian merit and should be abandoned.

The lengthy 1849 report can best be appreciated by placing it in the context of medical knowledge at that time. The germ theory of disease had not yet been advanced. Epidemics were thought to be the consequence of noxious atmospheric irregularities [miasmas] combined with ill-defined individual susceptibilities. The answer, they declared, rested in improved hygiene and community sanitation. Although their reasoning was faulty their health-protecting measures turned out to be reasonably successful.

It would be years before the mechanism of spread of these diseases was understood. Cholera was eventually shown to be disseminated not by touch but by contaminated drinking water, typhus by the interpersonal migration of body lice, and yellow fever by the intercession of a mosquito carrying the virus from the afflicted to the susceptibles.

Only after quarantine had been discredited did the nations of the world finally agree, in 1909, to form an international office to monitor transnational interventions designed to suppress epidemics. It took centuries to learn that bacteria are not intimidated by national boundaries.

— Stanley M. Aronson, MD

Sports Medicine

The role of the physician caring for athletes is to educate, promote safety in sports participation, and injury prevention, in addition to the clinical diagnosis and treatment of athletic diseases and injuries. The dual role of educator and clinician makes office practice a challenge for all physicians, especially those treating athletes. Interest in fitness and athleticism continues to soar. "Athletes" of all ages, from pediatric to geriatric, with a broad spectrum of skill levels and expectations, have come to demand that their physicians will be available and able to

guide them in their athletic pursuits. The physicians' challenge is to remain one step ahead of these athletes while synthesizing a continually evolving knowledge based across multiple disciplines. In two issues of *Medicine & Health/Rhode Island* dedicated to Sports Medicine we hoped to provide a useful current concepts of clinical practice regarding some common problems encountered in primary care of the athlete. The February 2000 issue included the common problem of exercised-induced asthma, a review of athletic shoulder disorders, the impor-

tant topics of arrhythmia and sudden cardiac death, a critical review of HIV and infectious diseases in sports, and a timely warning regarding athletic ocular injuries. This month's issue is also diverse, with topics including drug abuse and doping, athletic knee injuries, problems unique to the female athlete, and the hazards of concussion head injuries.

We were pleased to have the opportunity to represent the Department of Orthopaedic Surgery at Brown University and Rhode Island Hospital as guest editors for these issues regarding Sports Medicine. Our job as editors was made easy by the uniformly outstanding transcripts submitted by the contributing authors.

— Michael J. Hulstyn, MD,
and Paul D. Fadale, MD

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Sports and Drugs in Primary Care

Albert J. Puerini, Jr., MD, FAAFP, and Kevin Gorey, ATC

The abuse of drugs and nutritional supplements represents one of the greatest challenges in the care of healthy athletic-minded patients of all ages.

The problem dates back at least 2700 years, to the first Olympic Games, when, to enhance performance, ancient Greek Olympians ate mushrooms. Aztec athletes, also to enhance performance, ate coca leaves. Drugs often do enhance performance, but some of those same drugs can have dire consequences. In the 1967 Tour de France, British cyclist Tony Simpson died after ingesting amphetamines.¹⁴ East German women athletes given steroids developed severe endocrine disturbances and have had increased numbers of malformed babies.

The list of potentially abusable substances in sports is huge. In this article, we will not attempt an exhaustive review of ergogenic aids, but will highlight substances of most relevance to physicians in the primary care setting.

PHARMACOLOGICAL AGENTS

Steroids

Steroids became popular in American sports after the 1956 Olympic Games, when American physician John Ziegler observed the improved performance of Soviet athletes, resulting from testosterone use. Ziegler then helped develop Dianabol®, a drug that became extremely popular with American athletes. After years of use and abuse of this substance, Dr. Ziegler openly regretted its development for the rest of his life. After widespread use in collegiate sports in the 1960s, the NCAA (National Collegiate Athletic Association) banned the use of steroids in 1973. In 1976, the Olympics banned steroids and instituted official drug testing during the Olympic Games. In 1990, President Bush signed the Anabolic Steroids Control Act, which made the illicit and inap-

propriate distribution of steroids a felony.

Anabolic steroids are more appropriately termed androgenic-anabolic steroids because in their natural state they include both androgenic (masculinizing) and anabolic (building) properties. Synthetic steroids have been designed to maximize the anabolic effects while minimizing the androgenic effects.

Initially, when sports medicine experts began studying the effects of steroids on performance, they claimed that the steroids did not increase strength - a claim that diminished the credibility of the experts. In fact, these substances significantly increase muscle mass and strength (when combined with exercise). In one placebo-controlled study, male weight-lifters increased muscle mass by an average of 13 pounds and bench-pressed an extra 48 pounds after only 10 weeks.⁶

Steroids increase protein synthesis in the muscle. They block the catabolic effect of glucocorticoids, thereby increasing the amounts of anabolic/androgenic hormone available. Their ability to enhance aggressive behavior may promote a greater intensity in training.

Steroids have been shown to increase erythropoiesis, improving oxygen transport. Through their anti-catabolic effects they are able to increase exercise tolerance, intensity, and endurance, as well as decrease recovery time.

Currently anabolic/androgenic steroids are approved for use in hypotestosteronemia, certain anemias, metastatic breast cancer, hereditary angioedema, endometriosis, and fibrocystic breast disease.

There are more than 40 steroid preparations on the market. They come in oral, parenteral, transdermal, and intranasal forms. Street terms include "juice," "roids," "crank," "D-ball," and "monkey ball."

Abbreviations Used:

ADP	adenosine diphosphate
ATP	adenosine triphosphate
NCAA	National Collegiate Athletic Association
NFL	National Football League

They are used in a variety of ways: continuous dosing; cycling on and off the drug; stacking (the use of more than one type of steroid in staggered cycles); pyramiding (a gradual increase in dose followed by a gradual taper). An array is the use of multiple drugs to enhance the total effect or to counteract side effects.

The negative effects of steroids have been clearly documented. They significantly decrease HDL levels and increase LDL and triglycerides, producing a potential increase in cardiovascular risk. They cause altered glucose tolerance and can increase blood pressure. They can cause acne and accelerate male pattern baldness. Gynecomastia is common. The risk of HIV and hepatitis increases with shared needle use. The oral forms are associated with peliosis hepatitis, cholestatic jaundice, and hepatocellular adenoma and carcinoma. Infertility is also seen.

Central nervous system affects include increased aggression, so called "roid rage," depression, mania, psychosis, and increased libido. The changes are similar in females and males.

In 1987 a survey published in *The Journal of the American Medical Association* found that 7% of all high school males had used steroids.³ Any otherwise healthy athlete exhibiting a combination of the above signs and symptoms should raise the physician's suspicion of steroid use and stimulate further investigation.

Because of the prevalence of their use in sports at all levels, physicians are obligated to maintain a high level of

suspicion and must educate athletes to the serious dangers of steroid use. (In the primary care setting, blood or urine testing is not useful.)

Amphetamines

Amphetamines were first used during World War II, when soldiers took them to increase alertness.⁹ Today, although amphetamines are controlled prescription drugs, they are commonly used by athletes at all levels.

Structurally, they are similar to endogenous catecholamines, such as epinephrine. Their mechanism of action is stimulation of the sympathetic nervous system, through the release of norepinephrine.

As a result of this action, athletes perceive a delay in the onset of fatigue or exhaustion. There also may be a delay in pain perception. Generally, skills such as speed, power, endurance, and concentration may be mildly enhanced during the peak effect, one to two hours after ingestion.

However, amphetamine use is inherently dangerous. Deaths have been reported in athletes due to its use. Because it induces hypertension and tachycardia, its use places excessive stress on the cardiovascular system, already stressed by exercise. Its ability to delay the sensation of fatigue may allow the athlete to push dangerously beyond normal limits, increasing the possibility of heat injury and circulatory failure. Other side effects include irritability, insomnia, angina, cardiac arrhythmia, headache, and cerebral hemorrhage. Excess use leads to psy-

chosis, and acute withdrawal may precipitate serious depression.

There are more than 40 steroid preparations on the market. . . . Street terms include "juice," "roids," "crank," "D-ball," and "monkey ball."



Cocaine

Because cocaine is one of the leading recreational drugs, athletes may use it both for recreation and for competition. Cocaine can not only enhance athletic performance, but also bolster confidence. Its mechanism of action is inhibition of the re-uptake of norepinephrine and dopamine. A 1986 survey of the National Football League identified it as the most commonly abused drug.⁷

There are no well-controlled studies on the ergogenic potential of cocaine. Therefore, little is known of its effect on athletic performance.

Although cocaine use by athletes has become far too common, most is recreational. However, some athletes believe cocaine to be ergogenic. The drug creates an intense euphoria that is thought to increase self-confidence and motivation. Like amphetamines, cocaine masks both fatigue and pain, increases alertness, makes the athlete feel energetic, and has strong addictive potential.

Athletes must recognize that even if cocaine use could bolster athletic performance, the risks far outweigh the benefits. Deaths of some prominent sports figures have been directly attributed to cocaine use.

The most dramatic danger of cocaine use is sudden cardiac death. Strokes have been reported. Smoked "crack" cocaine is even more dangerous because its rapid absorption intensifies its effects.

Alcohol

Alcohol consumption is the #1 drug problem in the United States today. Some athletes use alcohol primarily for its psychological effects. The athletes believe that alcohol bolsters self-confidence, calms the nerves, reduces inhibitions, and makes them more alert. Studies, though, suggest that alcohol impairs most psychomotor functions associated with sport performance.⁵ Although athletes can feel more alert and self-confident, their reaction time, coordination, movement and thinking are impaired. Well-controlled studies consistently support the conclusion that alcohol ingestion has no ergogenic effects on strength, power, speed, local muscle endurance, or cardiorespiratory endurance.¹⁴

More important than its lack of ergogenic qualities, alcohol has many ergolytic features. Its depressant effects on the central nervous system dull pain sensation; but pain indicates injury; and the athlete who continues with physical activity while injured always risks increasing the extent of the injury. Alcohol suppresses the release of antidiuretic hormone, causing the body to excrete more water in the urine. This can transiently decrease blood pressure and cause dehydration. Alcohol also causes peripheral vasodilation, which can trigger hypothermia in cold environments.

Diuretics

Diuretics are used in sports primarily in two settings.

First, in sports where competitors are matched by weight divisions, such as wrestling, boxing, and weightlifting, diuretics are used to promote a forced rapid weight loss.

Second, some athletes feel that by increasing urine volume they can dilute concentration of other banned substances, making their detection more difficult. However, with the increased technology and specificity of drug testing, this is not likely to be effective.

Diuretics lead to significant weight loss, but no evidence suggests any potentially ergogenic effects. In



fact, several side effects make the diuretics ergolytic. The fluid loss results primarily from losses in extra cellular fluid. For athletes, particularly those dependent on moderate to high levels of endurance, this reduction in plasma volume reduces maximal cardiac output, which in turn reduces aerobic capacity and ultimately impairs performance.

NUTRITIONAL SUPPLEMENTS

Creatine

Creatine is one of the most widely used legal supplements available to athletes today. An estimated 30%-50% of professional athletes use it on a regular basis. Some professional teams have tubs of creatine in their locker rooms. It first became popular after the 1992 summer Olympic games in Barcelona, when gold medalists Linford Christie (100-meter dash) and Sally Gunne (400-meter hurdles) credited their quick recovery and increased training to creatine. The NFL's Troy Aikman and John Elway, as well as major league baseball's home run king Mark McGuire, use it openly. Bodybuilders, sprinters, boxers, weekend athletes and student athletes use a variety of forms in a variety of doses.

According to the *Nutrition Business Journal*, the sale of creatine was expected to surpass \$200 million in 1998.¹⁶ Although it is not condoned on the college and high school level, it is readily available to any athlete.

Creatine is a naturally occurring substance in the body. It is derived from amino acids and produced naturally in the liver, kidney, and pancreas. It is also found in meat and fish.

Creatine binds phosphate to form creatine phosphate. During brief intense anaerobic actions, such as sprinting and weightlifting, creatine phosphate facilitates the conversion of ADP to ATP. The result is more energy to sustain these powerful muscle contractions. Many athletes believe that supplemental creatine may speed up this refueling process when one needs quick repetitive explosive energy. Also, creatine phosphate buffers the intracellular hydrogen ions associated with

lactate production, thereby decreasing recovery time.

Ironically, those who use it most, probably benefit least, if at all. Many power athletes consume large amounts of fish and meat. There is a saturation point beyond which no further creatine can be stored in a muscle. Adding more beyond that point probably has minimal or no effect.

The issue of most concern is that large well-controlled studies are lacking. Numerous smaller studies report mixed results. Most of creatine's popularity stems from the plethora of anecdotal reports in health clubs and on athletic teams.

Potential side effects include nausea, diarrhea, weight gain from the increased water in muscle cells, dehydration and muscle cramping in the torso and large muscles. Tightness of the hamstring muscles has been frequently reported.

The real problem, however, may be not in what we know about creatine, but in what we do not know. There is no available data on long-term effects of regular ingestion. The primary concern is its effects on heart muscle and kidneys after long-term regular use, especially by rapidly growing adolescents.

The FDA (Food and Drug Administration) recommends that creatine be used only with a physician's advice. However, its widespread availability makes it unlikely that athletes will ask their doctors. In fact, most informed physicians do not recommend its use. Clearly, more needs to be learned about this supplement. It is the physician's responsibility to inform his athletic patients of the potential risks, benefits, and side effects of creatine use.

Androstenedione

Androstenedione, often called "Andro," also occurs naturally in the body. It is produced in the adrenal glands and in the gonads, found naturally in some meats and plants, and can be produced synthetically. It is readily available in most retail stores. Androstenedione is a metabolic precursor to testosterone. Athletes who use andros-

tenedione typically experience transient elevations of their testosterone levels. More testosterone can translate into more muscle mass and more strength.

While manufacturers of androstenedione say it does not pose the same hazards as anabolic steroids, the Association of Professional Team Physicians has cautioned that "its chemical structure is that of a steroid and possible side effects may be similar to those of anabolic steroids." A recent study in *JAMA* found that androstenedione given to 20 men in an 8-week weight training program produced no change in muscle strength and testosterone levels as compared to men in a placebo group.¹⁷

The FDA classifies androstenedione as a dietary supplement. The International Olympic Committee, the National Collegiate Athletic Association, and the National Football League ban it. Major league baseball allows it.

Although androstenedione has been available for over 60 years, there are very few well-controlled studies describing its benefits and risks. This supplement potentially has more serious implications than creatine and should be discouraged.

Other Supplements

Amino acids, aspartates, boron, caffeine, carnitine, chromium, co-enzyme Q, DHEA, Ginseng, Ma Huang and Yohime are just a few of the hundreds of supplements that promise to enhance athletes' performance. Their street names - "Andro fire," "Lean Machine," "Whey Beyond," and "Muscle Max" - beckon athletes to spend hundreds of dollars monthly.

These aids can be costly and potentially harmful. No clear benefits have been documented in any reliable study.

Unfortunately, these supplements are subject to little regulation by the FDA.

L-Tryptophan ingestion was linked to multiple cases of eosinophilia myalgia syndrome and 32 deaths due to contamination by the manufacturer. Gamma-butyrolactone, an ingredient in many supplements found in health

clubs, was recently recalled by the FDA because of 55 serious adverse incidents, such as loss of consciousness, coma, respiratory failure, seizures, mental status changes, and one death. These examples illustrate the quality and purity concerns of unregulated "nutritional aid" supplements. As a rule, these agents should be strongly discouraged until further research documents their safety and efficacy.

CONCLUSION

Unfortunately, drug testing is not done in high schools, is performed only occasionally on the collegiate level, and even at the Olympic level is random and disorganized. For the physician, drug testing is not the answer. In addition, nutritional supplements are available to all, although there is little proof of their efficacy and even less is known of their potential dangers.

The desire to win leads athletes to look for anything to improve their performance. As a result, aggressive advertising aimed at high school, college and recreational athletes has spurred retail sales of dietary supplements alone to \$3.3 billion in 1990.² Revenues increase yearly.

The clinician needs to educate him/herself and then his/her athletic patients to the uselessness and inher-

ent dangers of pharmacological agents and nutritional supplements promoted as ergogenic aids. This is a formidable task. However, amidst the availability, questionable value, and potential dangers of ergogenic aids, one dictum remains clear. For a well-defined and healthy body there are absolutely no substitutes for a balanced diet, adequate fluid intake, and a proper exercise program.

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FORTHCOMING: Blood-Borne Pathogens: A CME Issue

Medicine & Health/Rhode Island is pleased to dedicate the July 2000 issue to blood-borne pathogens. This issue will be guest-edited by Marguerite Neill, MD.

Brown University School of Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide Continuing Medical Education for physicians.

Brown University School of Medicine designates this educational activity for a maximum of 2 hours in Category 1 credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

This satisfies the State of Rhode Island's requirements for 2 credits in blood borne pathogens.



Concussion and Head Injury

Paola Santalucia, MD, and Edward Feldmann, MD

Head injury is a major public health problem and a common cause of death and disability in young people. In the USA, head injuries place considerable demands on health services.¹ The annual incidence of traumatic brain injury in the USA varies from 175 to 367 per 100,000 population. Each year, in the USA head injuries cause 100,000 deaths and permanent disability in 75,000 people.² Head injuries occur at all ages, but the peak is in young adults between the ages of 15 and 24.³ An estimated 300,000 sports-related head injuries, most of which can be classified as concussions, occur in the United States each year.^{4,5}

Head injury presents with a wide range of severity. Some patients die before admission to the hospital. Others have head trauma so mild that they do not even come to medical attention at the time of initial injury. Instead, they present to their primary care physician days, weeks or even months later. In between these extremes are those in coma, either initially or as a result of complications, those with moderate to severe head injury admitted to the hospital, and a larger number who are discharged home from the Emergency Department.¹

Traumatic head injury occurs as a result of violent contact forces or rapid acceleration/deceleration movements of the head, with or without evidence

of external trauma. Some degree of disturbance of consciousness is the most common symptom of head injury, ranging from brief loss of contact with the environment to coma. Coma may be prolonged, lasting for several hours, days, or even weeks when there is brain swelling, hemorrhage, diffuse axonal injury (DAI), contusion or laceration of the cerebral cortex.³

The severity of traumatic brain injury is classified by certain measures, including duration of loss of consciousness, duration of post-traumatic amnesia, and the Glasgow Coma Scale (GCS) score. Patients are typically classified as having a concussion versus a severe head injury. Subdividing patients with a traumatic head injury into these categories facilitates determination of appropriate medical treatment and prognosis for recovery.⁶

CONCUSSION

The Quality Standard Subcommittee of the American Academy of Neurology has defined concussion as a "trauma-induced alteration in mental status that may or may not involve loss of consciousness."⁷ The term brain concussion is often used in the literature as a synonym for mild traumatic brain injury (MTBI) and implies a transient disturbance of neuronal function secondary to mechanical forces. MTBI has been defined by the Ameri-

Abbreviations Used:

CT	computed tomography
DAI	diffuse axonal injury
EDH	epidural hemorrhage
GCS	Glasgow Coma Scale
MRI	magnetic resonance imaging
MTBI	mild traumatic brain injury
PCS	postconcussion syndrome
SAH	subarachnoid hemorrhage
SDH	subdural hemorrhage

can Congress of Rehabilitation in 1993 as "head trauma with loss of consciousness lasting less than 30 minutes, a Glasgow Coma Scale (GCS) score of 13 or more and post traumatic amnesia lasting less than 24 hours."⁸ The typical patient with MTBI suffers a brain concussion.

The mechanism of a concussion is a change in the momentum of the head. Either movement is imparted to the head by a blow or movement of the head is arrested by a hard, unyielding surface. These two types of blunt head injury are called accelerative and decelerative, respectively.⁹ In football, for example, accelerative forces are generated when an opponent or the ball hits an athlete's head. The site of maximal injury is usually beneath the point of cranial impact (coup injury). Decelerative forces, which are generated when an athlete's head strikes the ground or some stationary object, produces maximal brain injury opposite the site of cranial impact (contrecoup injury).¹⁰ The severity of the concussion is only roughly proportional to the magnitude of the applied traumatic force.

Confusion and memory dysfunction commonly follow a concussion, either immediately after the blow to the head or several minutes later. Therefore, close observation and careful examination of the patient are necessary. The main features of confusion include: 1) disturbance of vigilance, distractibility; 2) inability to maintain a

Table 1. Grading scale for severity of concussion⁷

GRADE I	<ul style="list-style-type: none">• Transient confusion• No loss of consciousness• Concussion symptoms or mental status abnormalities on examination resolve in less than 15 minutes
GRADE II	<ul style="list-style-type: none">• Transient confusion• No loss of consciousness• Concussion symptoms or mental status abnormalities on examination last more than 15 minutes
GRADE III	<ul style="list-style-type: none">• Any loss of consciousness, either brief (seconds) or prolonged (minutes)

Table 2. Sideline examination in evaluation of concussion.

• ORIENTATION	Time Place Person Circumstances of injury
• CONCENTRATION	Repetition of digits backwards Months of the year in reverse order
• IMMEDIATE MEMORY	Names of the teams Details about the game
• DELAYED RECALL	Recall of 3 words at 0 and 5 minutes
• NEUROLOGICAL EXAMINATION	
• EXERTIONAL TESTS	

coherent sequence of thought; 3) inability to carry out a set of goal-directed movements. Memory dysfunction may involve memory loss for the events following the injury (post-traumatic or anterograde amnesia), for events preceding the injury (retrograde amnesia) or failure to retain new information.¹¹ A grading scale to determine the severity of concussion has been established by a consensus of experts who reviewed all existing scales. This scale has been used in sports medicine (Table 1).⁷

EVALUATION OF CONCUSSION

Concussions must be carefully recognized and evaluated in order to assess their severity. In sports-related head injuries, proper evaluation will decide whether the athlete has an immediate or delayed return to competition. In a Grade I concussion, the athlete is never unconscious and suffers only momentary confusion or mental status alterations. Players commonly refer to this state as having been "dinged" or having their "bell rung". In a Grade II concussion, there is also no loss of consciousness, but the athlete experiences symptoms or exhibits signs of mental status alterations that last longer than 15 minutes. Any persistent Grade II symptoms (greater than 1 hour) warrant medical observation and neurological examination. Grade III concussion is usually easy to recognize. The athlete is unconscious

for some period of time.⁷ Early (minutes to hours) symptoms following any concussion may include headache, dizziness, nausea, vomiting, slurred speech, imbalance and incoordination. Late (days to weeks) symptoms include persistent low-grade headache, poor attention and concentration, memory dysfunction, easy fatigability, irritability, anxiety and depressed mood, and sleep disturbance.^{6,11}

Neuroimaging plays an important role in the evaluation of head injury.



Assessment of any potential brain damage after concussion is best achieved by a clinical examination immediately after the event. A standardized sideline evaluation for immediate assessment of concussion in athletes has

been proposed.¹² The sideline examination, according to the Colorado Medical Society and American Academy of Neurology Guidelines, contains four components: orientation (to time, place, person, and circumstances of injury), concentration (repetition of digits backwards, months of the year in reverse order), immediate memory (names of the teams or details about the game), and delayed recall (recall of 3 words at 0 and 5 minutes). Neurological examination of pupils (symmetry and reaction), strength, sensation and coordination should be performed along with exertional tests (40-yard sprint, sit-ups, push-ups, knee bends) in order to assess the physical condition of the athlete at rest and on exertion (Table 2).^{7,11,12} The possibility of a skull fracture should always be ruled out. Findings that may point to a skull fracture include postauricular hematoma, otorrhea, rhinorrhea, "raccoon eyes", hemotympanum, and visual disturbances due to optic nerve damage.¹⁰

MANAGEMENT OF CONCUSSION

The management of concussion is determined by its severity (Table 3). Initial treatment of a Grade I concussion requires the player to be removed from the game and observed on the bench. After a sufficient period of time (15 to 30 minutes), if the athlete remains asymptomatic, both at rest and on exertion, and has full recall for events that occurred just before the injury, return to the game may be considered. This assumes the athlete has not sustained any neck injury. If an athlete has any symptoms during either rest or exertion, or if his performance is impaired, continued neurological observation is essential.

Table 3. Management of concussion according to its severity.

GRADE I	<ul style="list-style-type: none"> • Remove the athlete from the game • May return to play if asymptomatic after 15-30 minutes
GRADE II and III	<ul style="list-style-type: none"> • Locate the athlete on a fracture board • Immobilize head and neck • Remove the athlete from the game • Neurological and/or neurosurgical evaluation at a medical facility

Table 4. Glasgow Coma Scale (GCS).

Eye opening	None	1
	In response to pain	2
	In response to verbal command	3
	Spontaneous	4
Verbal response	None	1
	Incomprehensible sounds	2
	Inappropriate words	3
	Confused	4
	Oriented	5
Motor response	None	1
	Abnormal extension	2
	Abnormal flexion	3
	Withdrawal	4
	To a localized stimulus	5
	To verbal command	6

Total= 3-15

The initial management of Grade II and Grade III concussion is identical to management of a suspected cervical spine fracture. The athlete should be located on a fracture board with head and neck immobilized, removed from the game and evaluated by a neurologist or neurosurgeon at a medical facility.

Neuroimaging plays an important role in the evaluation of head injury. With uncomplicated brain concussion, there is usually no structural brain injury evident on MRI or CT scans. However, it is important for clinicians to realize that any brain concussion may be complicated by coexistent cortical contusion or development of in-

tracranial hemorrhage.⁶ Worrisome signs or symptoms must be identified quickly, and evidence of intracranial pathology must be sought for and dealt with emergently. Prolonged unconsciousness, persistent mental status alteration, worsening post-concussion symptoms, or abnormalities on neurologic examination require urgent neurosurgical consultation and emergent imaging.¹¹ In every patient suffering from Grade II and III concussions, possible intracranial bleeding should be ruled out.¹³ A non-contrast CT scan of the head is the study of choice. Intracranial bleeding, evolving cerebral edema associated with cortical contusions or diffuse axonal injury may account for progressive deterioration in neurological function. Patients with concussion should be admitted for observation if in the Emergency Department they manifest confusion, lethargy, a GCS score of less than 15 (Table 4), abnormal findings on CT scans, and/or focal neurological signs.⁶

RETURN TO COMPETITION

Guidelines for return to competition are not only based on the severity of an individual concussion, but also on the incidence of prior concussions (Table 5). In Grade I concussion, return to competition must be deferred until all symptoms (headache, dizziness, impaired orientation, concentration, memory) have resolved, at rest and during exertion. A second such mild concussion mandates removal from competition for at least two weeks, and return at that time is advisable only if the athlete is asymptomatic at rest and during exertion for at least one week. Three mild concussions should terminate a player's season.

Following a first concussion of Grade II severity, return to competition may occur as soon as one week after the athlete is asymptomatic both at rest and on exertion. After a second such moderate concussion, return to play should be deferred for at least one month, and termination of the season should be considered. Three moderate concussions mandate termination of the season, as would an abnormality on a CT scan or MRI.

After a Grade III concussion, the athlete must not be allowed to play for at least one month. Return is allowed at that time only if the athlete has been asymptomatic at rest and on exertion for at least one week. Two severe concussions or any neuroimaging abnormality should terminate the season. If asymptomatic at rest and exertion, an

Table 5. Guidelines for return to competition after head injury^{13,14}

	1 ST CONCUSSION	2 ND CONCUSSION	3 RD CONCUSSION
• GRADE I	<ul style="list-style-type: none"> ◦ Remove from competition ◦ May return to play if asymptomatic after 15-30 minutes 	<ul style="list-style-type: none"> ◦ Remove from competition for at least 2 weeks ◦ May return to play if asymptomatic for at least 1 week 	<ul style="list-style-type: none"> ◦ Terminate player's season ◦ May return to play if asymptomatic for 3 months
• GRADE II	<ul style="list-style-type: none"> ◦ Remove from competition ◦ May return to play if asymptomatic for at least 1 week 	<ul style="list-style-type: none"> ◦ Remove from competition ◦ May return to play if asymptomatic for at least 1 month 	<ul style="list-style-type: none"> ◦ Terminate player's season ◦ May return to play next season if asymptomatic
• GRADE III	<ul style="list-style-type: none"> ◦ Remove from competition ◦ May return to play in a 1 month if asymptomatic for at least 2 consecutive weeks 	<ul style="list-style-type: none"> ◦ Terminate player's season ◦ May return to play next season if asymptomatic 	<ul style="list-style-type: none"> ◦ Terminate player's season ◦ Discourage the athlete from returning to competition in contact sports

athlete whose season was terminated according to these criteria may return to play the next season. An athlete who had had 3 such concussions or who requires intracranial surgery or has hydrocephalus should be discouraged from returning to competition in contact sports.^{13,14}

SECOND IMPACT SYNDROME

The second impact syndrome describes a concussion that occurs while an individual is still symptomatic from an earlier one. Specifically, the second impact syndrome has been defined as occurring when "an athlete who has sustained an initial head injury, most often a concussion, sustains a second head injury before symptoms associated with the first have fully cleared."^{15,16,17} This results in loss of cerebrovascular autoregulation and progressive cerebral edema. Cerebrovascular congestion resulting from the second impact syndrome may be detectable on head CT scans.⁶ Such diffuse cerebral swelling is well recognized cause of catastrophic deterioration resulting in death or persistent vegetative state after an apparently minor head injury.

The pathophysiology of second impact syndrome involves loss of autoregulation of the brain's blood supply, secondary vascular engorgement, and markedly increased intracranial pressure, which lead to herniation either of the medial surface (uncus) of the temporal lobe or lobes below the tentorium or of the cerebellar tonsils through the foramen magnum. The usual time from second impact to brainstem failure is rapid, about 2 to 5 minutes.¹⁸ This underscores the importance of removing athletes from competition until they are clearly asymptomatic.

POSTCONCUSSION SYNDROME

Postconcussion syndrome (PCS) refers to somatic, affective and cognitive symptoms that may complicate the recovery from a MTBI. These symptoms are often brought to the attention of primary care physicians days, weeks, or even months after the initial traumatic event. The most common

symptoms are headache and dizziness. Other symptoms include fatigue, concentration difficulty, sleep disturbances and emotional dysfunction.^{6,19} The clinical presentation of the PCS is remarkably consistent, although the reported incidence varies widely. PCS may be a persistent phenomenon for 6-12 months, or rarely years. PCS resists treatments but eventually the symptoms resolve. The cause of PCS is controversial. Its high frequency suggests that the cerebral insult is the principal cause. However, some experts believe that although PCS may initially have an organic basis, it may persist because of psychological factors.²⁰

SEVERE HEAD INJURY

Approximately 10% of head injuries are classified as severe.²¹ The most common severity classification employs the Glasgow Coma Scale,^{3,9} considering a score of 13-15 as mild, 9-12 as moderate, and 3-8 as severe. The GCS is useful for following the course and predicting the outcome of severe head injuries. For example, a score of less than 8 is typically associated with a poor prognosis for complete recovery.

Severe brain injury, in contrast to concussion, is associated with pathologic change in the brain. These changes are described in the sections that follow.

BRAIN CONTUSION

Contusions are areas of focal cortical injury that result either from direct external contact forces or from the brain being slapped against intracranial surfaces with acceleration/deceleration trauma. Commonly involved sites include the bases of the frontal and anterior temporal lobes.

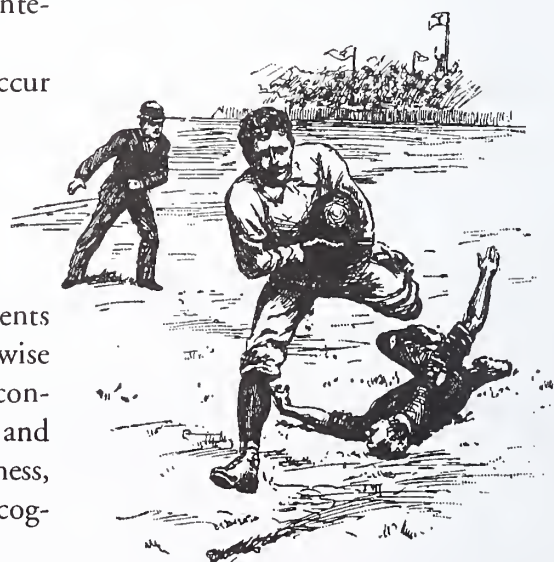
Parasagittal contusions may occur with whiplash injury and result from acceleration/deceleration of the head without direct impact. Contusions are associated with localized ischemia, edema, mass effect and poorer outcome in patients whose clinical presentation otherwise suggests only a MTBI. Signs of a contusion vary with cortical location and may include focal weakness, numbness, incoordination, and memory and cognition dysfunction.⁶

ACUTE EPIDURAL HEMORRHAGE

Epidural hemorrhage (EDH) is due to a temporal or parietal fracture with laceration of the middle meningeal artery. The classic case is that of a victim of head injury who was unconscious only momentarily. A few hours or a day later, after the so called "lucid interval" headache of increasing severity develops, with vomiting, drowsiness, confusion, aphasia, seizures, hemiparesis and development of coma. The pupil may dilate on the side of the hematoma. Death due to respiratory arrest is invariable if the clot is not removed surgically. The visualization of a fracture line across the course of the middle meningeal artery and knowledge of which side of the head was struck are of aid in diagnosis and lateralization of the lesion. The CT scan reveals a lens-shaped clot with a smooth inner margin.⁹

SUBDURAL HEMORRHAGE

Subdural hemorrhage (SDH) occurs when trauma tears the bridging veins in the subdural space with resulting hemorrhage between the brain surface and the durae. These hemorrhages may be acute, subacute, or chronic. In acute SDH there may be a brief lucid interval between the blow to the head and coma, but more often the patient is comatose from the time of the injury and the coma deepens progressively.⁹ In severe instances the underlying brain is often contused. Occasionally, the brain itself will not be injured, and the SDH develops slowly over a period of days to weeks. Such chronic SDHs are often associated with



headache and may cause a variety of very mild, almost imperceptible, mental, motor or sensory signs and symptoms.

SUBARACHNOID HEMORRHAGE

Subarachnoid hemorrhage (SAH) results from bleeding of small vessels coursing within the subarachnoid space. They are torn by shearing forces during the acceleration or deceleration phase of brain movement in the concussive episode. The history is often quite similar to that of patients with uncomplicated concussions.

Headache is the most common presenting complaint. Usually there is no evidence of focal neurological deficit. There is often a period of amnesia around the concussive event, both anterograde and retrograde. In the absence of more severe associated intracranial lesions, traumatic SAH generally has a benign clinical course.

DIFFUSE AXONAL INJURY

Diffuse axonal injury (DAI) is typically associated with a severe head injury with coma lasting longer than 6 hours. It is the result of shearing and stretching of neuronal axons. Neuroimaging typically reveal focal lesions less than 1 cm in diameter in the corpus callosum, the dorsolateral aspect of the rostral brain stem, and lobar white matter. Most of such lesions are nonhemorrhagic and best detected on MRI. When associated with prolonged coma, DAI usually has an unfavorable outcome.³

MANAGEMENT OF SEVERE HEAD INJURY

An examination should be performed at the scene of the accident before the patient is moved. A clear airway must be assured and pulse and blood pressure obtained. The head and neck must be immobilized. The depth of coma, size of the pupils and their reaction to light, ocular movements, corneal reflexes, reactions to the pain stimulation, muscle tone, predominant postures, and reflexes should be assessed. The scalp should be carefully inspected. Bogginess of the temporal or postauricular area (Battle's sign),

bleeding from the nose or ear, and extensive conjunctival edema and hemorrhage are useful signs of an underlying skull fracture. The Glasgow Coma Scale provides a practical means to evaluate the state of impaired consciousness at frequent intervals. Computed tomography is of central importance.²² Readily available at all major trauma centers, it is the study of choice for evaluating the extent of acute hemorrhage and skull fractures. In the presence of contusions, brain edema, and displacement of central structures it is crucial to monitor the progression of these lesions and to control the intracranial pressure. The clinical status of the patient and the results of neuroimaging establish the need for surgical intervention. The presence of epidural or subdural clot causing a shift of central brain structures calls for immediate evacuation.

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Common Athletic Knee Injuries

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Injuries to the knee are a common, highly publicized occurrence in athletic individuals. Recently, the identification of a higher rate of knee ligament injuries in female athletes at a time when women's sports is enjoying an explosion of popularity causes further concern.¹ Most often these patients will present to their primary care physician for initial evaluation. The history and physical exam remain the most accurate and cost-effective tool in evaluating the injured athlete. Furthermore, radiographic studies can only help confirm some of the many possible injury patterns and must not be solely relied upon.

Classically an anatomic approach to injury evaluation and treatment has been used to teach musculoskeletal pathology. However, these soft tissue injuries rarely occur in isolation, but commonly occur in combinations. The physical exam is the key in diagnosing these injuries and, thus, in choosing the proper treatment regimen for these patients. When examining the knee, it is imperative to have the patient relax as much as possible. Most athletes are well aware of the possible dysfunction following a serious knee injury and are apprehensive. Supporting the head and injured knee with a pillow, relaxing the abdominal muscles, and calming the patient prevent muscle spasm, which could make subtle ligamentous instability impossible to detect. Every knee exam should be done by examining the uninjured side first and then comparing the injured side to it. Only this comparison of normal to abnormal will accurately reflect the degree of injury.



ANTERIOR CRUCIATE LIGAMENT

The anterior cruciate ligament functions as the primary restraint to anterior tibial translation.² Initially it was taught that tears of the ACL occurred secondary to direct knee trauma such as can occur in football. Sports requiring twisting and deceleration are at highest risk for the production of an anterior cruciate ligament injury. Contact can cause but is not required to injure the ligament. When injured, the patient usually recalls hearing a pop and an effusion occurs within a few hours.³ There is a sensation that the knee "shifted" or "came apart". This classic presentation alone is greater than 70% accurate for the diagnosis of ACL disruption. These injuries are being seen with increasing frequency and can result in significant knee dysfunction. Unfortunately, these injuries continue to be diagnosed as "sprains" and are often missed. The initial swelling and pain will usually improve; this can result in cessation of the work-up. Unfortunately these injuries are permanent, often lead to progressive degeneration within the knee, or result in significant activity reduction for the patient. The treating physician must maintain a high degree of suspicion if he/she hopes to make the correct diagnosis.

If possible, immediate examination is often the most helpful and accurate before swelling and pain cause reflex muscle spasm. The examination begins with observation and palpation of an effusion. Lack of flexion is consistent with an effusion while lack of extension is consistent with a mechanical block such as an entrapped meniscal tear or stretching of a painful ACL disruption. The pathognomonic finding on physical examination for a torn ACL is a positive Lachman test. With the patient

Abbreviations Used:

ACL	anterior cruciate ligament
AP	anterior posterior
MCL	medial collateral ligament
MRI	magnetic resonance imaging

supine, and the knee flexed 20 degrees, the physician places one hand around the lower thigh, and the other around the upper leg. With the femur stabilized, the tibia is pulled forward. Normally there is only a trace of motion across the knee joint and a firm end-point is felt. With an ACL tear, there is increased excursion across the joint and the firm end point is replaced with a soft feeling at the extremes of motion.

The first test obtained is an x-ray. Suggested views include AP, lateral, sunrise, and 45 degree flexed weightbearing view. The pathognomonic, but uncommon, finding of ACL disruption is the Segond fracture off of the lateral tibial plateau. Avulsion of the tibial spine is more common in the pediatric population but can occur in adults. Today the most popular and most expensive study ordered for the evaluation of the injured knee is the MRI. Although the MRI need not routinely be used to make the diagnosis of ACL tear, it is useful for detecting concomitant injuries such as bone bruises or meniscal tears.⁴ The referring physician must know the accuracy of MRI reports in his/her setting as these can vary widely, and s/he should be able to read the film.

Because of its intra-articular location, the anterior cruciate ligament is unable to heal or be directly repaired. Once torn, it remains so. There are three general treatment category options for the ACL deficient patient.^{5,6} First, "conservative care" with activity modification is usually unacceptable to an athletic individual and may not be as benign as once

thought. There is a high likelihood of further knee instability, which can cause further damage within the knee. Therefore a second option of bracing in combination with physical therapy and exercise is the initial choice of many patients. Ultimately, strength of the injured limb should be at least 85% of the normal knee. Greater strength is desirable. A complete lower extremity rehabilitation program is necessary prior to returning to sports. Controversy has surrounded the use of braces.⁷ The accepted recommendation for their use has been brought into question because of minimal scientific support. Claims for their ability to "hold the knee together" and "protect the knee from further damage" have not been proven. Presently, many feel that braces do play a role in the care of knees that are not surgically repaired and function by proprioceptive facilitation of the thigh musculature. Realistic limitations of bracing must be honestly explained to the athlete, as the braces are unable to prevent knee subluxation or further injury under athletic loads. Again, if the knee remains unstable, there is concern for the development of further meniscal injury and early onset arthritis. Therefore, as a final option patients may seek surgical reconstruction. This option offers the greatest chance for athletes to return to high demand sports and therefore is becoming the most popular treatment option.

MEDIAL COLLATERAL LIGAMENT

The medial collateral ligament (MCL) is the most commonly injured knee ligament. The true incidence may never be known because the more frequent lesser grade injuries are never reported. Contrary to the ACL, the MCL is extra-articular and has tremendous capacity to heal. The major function of the MCL is to prevent the knee from buckling inward. Disruption of the MCL can occur with a valgus, external rotation force such as with skiing or with a straight lateral blow to the thigh or leg such as in football.⁸ Physical examination reveals tenderness along the ligament, espe-

cially at the point of disruption, which is most commonly at the medial femoral epicondyle. This spot is near the medial joint line, and care should be taken not to misdiagnose a medial meniscus tear. Often there is not a significant intraarticular effusion, and if found, injuries to the cruciate ligaments, patella, or meniscus should be sought. The mechanism of injury and physical findings can also be confused with a patella subluxation. Thus, patella apprehension with forced lateral displacement of the patella associated with medial retinaculum tenderness may identify an occult extensor mechanism injury. A more serious injury to be considered is an injury to the cruciate ligaments, especially the ACL. This can occur in conjunction with a medial collateral ligament tear.

Every knee exam should be done by examining the uninjured side first and then comparing the injured side to it.



Radiological evaluation is needed, especially in athletes with an open physis, to rule out a fracture such as seen with growth plate injuries in children. This more serious injury must not be missed and controlled stress x-rays should be considered. An MRI is rarely required for evaluation.

Treatment of isolated medial collateral ligament injuries is straightforward. If there are no associated problems, conservative treatment is the overwhelming choice of sports medicine physicians.⁹ Ice, compression, and elevation begin immediately. An aggressive rehabilitation program stressing painless range of motion, thigh strengthening, and proprioception is highly successful in returning the athlete to competition. Hinged braces with motion limited from 0 to 90 degrees early on in the rehab period may reduce stress on the healing

tissue. The need to reverse the atrophy of thigh musculature may further delay the return to sports. Corticosteroid injections should be avoided.¹⁰

MENISCUS

The most common disabling lesion in the knee is a torn meniscus. The menisci play a large role in load distribution as well as in assisting in maintaining knee stability. Clinical studies have supported the notion that a good history and appropriate physical examination is highly accurate in the diagnosis of a torn meniscus. Athletes will complain of sudden pain after a quick twisting or squatting knee motion. A rapid onset of swelling from a hemarthrosis can be caused by ACL tear, osteochondral injury, or a meniscal tear in the peripheral vascular zone. Delayed synovial effusions seen after a day or so are usually due to central meniscal tears in the avascular portion. Joint line pain and swelling will bring the athlete to seek further evaluation. Positive physical findings include an effusion, thigh atrophy, and joint line tenderness. McMurray testing is a provocative maneuver to recreate the offending pain. The knee is brought into full flexion. As the knee is extended a valgus, external rotation force is applied. This is repeated with a varus, internal rotation force. Either a palpable click or pain is elicited as the offending meniscal fragment is caught and displaced. Bucket-handle tears trapped within the knee characteristically cause locking with inability to fully extend or flex the knee. Flexed weight bearing PA, lateral, and sunrise x-rays are obtained if the above physical findings are positive. If needed, objective confirmation by MRI can be ordered.

Treatment of a torn meniscus has advanced from pursuing pain relief with a complete meniscectomy to the possibility of preservation of normal knee function by meniscal repair.¹¹ A number of injuries will become quiescent and remain asymptomatic. For those that remain painful, arthroscopic intervention is required. Tears in the vascular peripheral zone of the meniscus may be amenable to

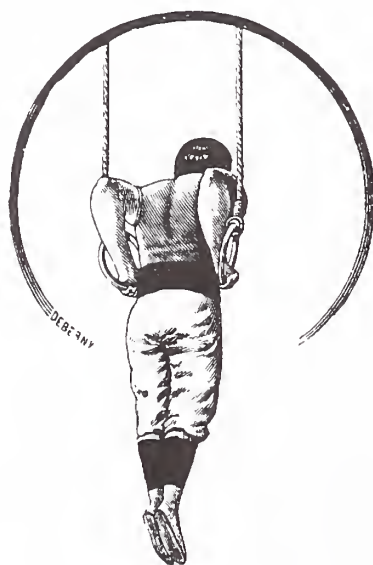
repair while the more common complex tears or tears in the avascular central zone are usually trimmed smooth to prevent propagation.

PATELLOFEMORAL JOINT

It is unfortunate that with so many advancements in our understanding of knee pathology, objective information regarding the patellofemoral joint lags so far behind. Patellofemoral disorders continue to be the most common, least appreciated, and least understood of all sports related injuries to the knee. This disorder is more common in young female athletes. This complex area of study lacks a clear scientifically supported consensus on diagnosis or treatment.¹² None the less, certain assumptions have been accepted.

Patella maltracking in the femoral trochlea is thought to be the most common cause of anterior knee pain. Stress is generated in the hyaline articular surfaces and subchondral bone of both the patella and the distal femoral trochlea. Most female athletes have valgus alignment to their knees resulting in lateral patella displacement with quadriceps muscle contraction. This mismatch leads to high contact pressures and pain. Medial patellofemoral and patellotibial ligaments are static stabilizers to lateral patella subluxation and may stretched with chronic stress, or can be injured by direct athletic trauma.

The history should differentiate pain from instability. Pain disorders commonly present as bilateral discomfort.



fort. The pain is vaguely defined as "around the front of the knee", is usually not localized, and is atraumatic. Pain is activity related and rest relieves it. Increased patellofemoral loading such as with prolonged sitting, stair climbing or running, and hiking will increase the pain. With the athlete sitting in front of the examiner the patella should face forward and not point in a laterally subluxed position. Patella tracking from flexion into full extension has been likened to an inverted J. Exaggeration of this course laterally in the last 30 degrees of extension as the patella exits the femoral trochlea indicates increased lateral forces upon the patella. The patella can be displaced for palpation of the medial and lateral facets. With an unstable patella a sense of apprehension will occur with a laterally directed force. Passive lateral patella subluxation is greater than three quarters of patella width is pathological. The lateral patella can be everted for measurement of patella tilt for the assessment of lateral soft tissue tightness. Patella tendonitis can be missed unless the inferior pole of the patella is lifted up by downward pressure on the proximal pole. Palpation of the inferior patella bone - tendon junction will bring out the tendonitis discomfort. Soft tissue tightness of the hamstring tendons and iliotibial band is a common finding in these patients. With the patient supine and the hip flexed to 90 degrees the athlete is asked to straighten the leg to the ceiling. Hamstring tightness precludes this and residual knee flexion is measured and recorded as the popliteal angle.

Fortunately conservative treatment should alleviate a significant amount of pain in the majority of patients.¹³ Activity modification will be needed initially and if poorly accepted, then cross training in a less stressful activity is encouraged. Therapy is directed towards full flexibility of the lower extremity including the iliotibial band, quadriceps, hamstrings, and calf muscles. Strengthening of the quadriceps and stretching of the lateral patella reti-

naculum can help center the patella. McConnell taping or patella bracing may augment this soft tissue realignment.^{14,15} Orthotic control of foot deformity can be successful in the appropriate athlete. Treatment with nonsteroidal anti-inflammatory medication should be for a short period only as success will come with rehabilitation, not drugs.

Lateral patella instability can occur with a twisting, external rotation motion accompanied by a strong quadriceps contracture. The patella may transiently dislocate laterally with spontaneous relocation upon straightening the knee. If this occurs, the patient or the follow-up physician may not appreciate the true significance of this injury. Often there is a hemarthrosis secondary to the high shearing forces producing an osteochondral fracture. The athlete exhibits apprehension when the patella is displaced laterally and tenderness along the medial patella and retinaculum. This retinacular pain can be confused with medial joint line discomfort. The ligament exam is stable. High quality x-rays with sunrise and oblique views may show an osteochondral fragment or significant malalignment. Treatment for an acute dislocation is with a brief period of immobilization for pain relief. Ice, compression, elevation and aspiration of the hemarthrosis, if significant, accompany the immobilization. If there are no intraarticular fragments than a progressive functional rehabilitation program is instituted. Once there is complete resolution of swelling, full range of painless motion, and equal quadriceps strength, the athlete is ready to return to sports. Patella bracing or taping is used early on. If the instability is chronic or intraarticular fragments are identified, then surgical intervention for patella realignment is required.

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The Female Athletic Triad

Kathleen A. Hogan, Paul Fadale, MD, Michael Hulstyn, MD

Bigger, faster, stronger. These are goals of athletes at every level of competition, from youth soccer to professional basketball. Athletes today run faster, hit tennis balls harder, throw faster, and jump further and higher than ever before. Improvements in equipment, training techniques, and physical conditioning have helped men and women to shatter performance records. Women in particular are discovering an explosion of athletic opportunities at the professional, collegiate, and youth levels of competition. This increase in the numbers of women participating in sports has led to a growing awareness among physicians of gender-related variability in sports injuries. In 1992, the American College of Sports Medicine used the term "female athletic triad" to describe a serious combination of disordered eating habits, amenorrhea, and osteoporosis which can develop in female athletes who exercise excessively. While participation in regular exercise can have significant health benefits, these female athletes may be causing potentially irreversible, long-term damage to their bodies. For example, peak bone mineral density is typically achieved by age twenty-five. However, hormonal imbalances, triggered by extremely low body weight, may cause a significant decline in peak bone density in young athletes. These

women are not only at increased risk for stress fractures but also for the early onset of osteoporosis as they age. Physicians need to be aware of the potentially devastating consequences of this syndrome. This article will explain the three elements of the female athletic triad, the potential risks to the athlete, and treatment options.

EATING DISORDERS

In some sports, such as gymnastics, diving, figure skating, and running, athletic performance is often closely linked to body weight. An athlete may view her weight merely as a performance variable that she is able to control. Coaches can also pressure athletes by requiring regular weight checks or setting body weight goals for their players. Being thinner is equated with being faster or stronger by both coaches and athletes. These statements are supported by multiple studies, which have demonstrated that female athletes have a significantly higher prevalence of eating disorders when compared to the general population. For example, Garner and Garfinkel studied 183 professional dancers utilizing surveys and height and weight data. These dancers had a 6.5% rate of anorexia with 38% of study participants meeting at least one criteria for anorexia.⁴ In a much larger study, Sundgot-

Abbreviations Used:

DSM	Diagnostic and Statistical Manual
DXA	dual energy x-ray absorptiometry
FSH	follicle-stimulating hormone
HDL	high density lipoprotein
LDL	low density lipoprotein
LH	luteinizing hormone

Borgen found an 11% prevalence of anorexia and/or bulimia in a group of 603 Norwegian elite female athletes. Additionally, 22% of the athletes were considered to be at high risk for having an eating disorder.¹⁴ In comparison, there is a 1% incidence of anorexia in the general population.⁶

The DSM IV sets four criteria for the diagnosis of anorexia nervosa: refusal to maintain body weight at 85% of expected for height and weight, fear of gaining weight, disturbed view of one's weight, and amenorrhea. Bulimia nervosa, in contrast, is defined as "recurrent episodes of binge eating" occurring for at least twice a week for three months. One will eat an inappropriate amount of food and then attempt to compensate by inducing vomiting, using laxatives or diuretics, or exercising to excess.¹ The majority of athletes with disordered eating patterns may have some elements of bulimia and/or anorexia but will not fulfill all of the criteria.

If weight loss will indeed increase one's speed in the 800 meter run, what harm is there in losing a few pounds? Problems arise not when one loses a few pounds through dieting, but when the goal of an ideal weight continuously decreases and eventually becomes unattainable. Despite perceived improvements in performance, these patterns of disordered eating can have severe physical consequences. In severe cases of eating disorders, endocrine and gastrointestinal dysfunctions are common. Other



symptoms of malnutrition, such as bradycardia, hypothermia, hypotension, mitral valve prolapse, and hypoalbuminemia may occur. Depression is also common among patients with eating disorders. In extreme cases, there is a risk of death from arrhythmias when body weight falls below 35% of the ideal weight for height.⁶

Some psychological and physical signs which may indicate that an athlete is developing an eating disorder include the following: obsession with body image, preoccupation with weight or dieting, excessive fatigue, hypothermia, guilt regarding eating, gastro-intestinal complaints, or signs of malnutrition such as loss of subcutaneous fat, hair loss, or an increase in fine body hair.⁵ An athlete with an eating disorder may deny the damage she is doing to her body and insist that her athletic achievements have improved secondarily to the loss of weight. Women who have eating disorders need to be counseled as to the harmful effects on their bodies. A balanced diet consisting of carbohydrates, protein, and fat is essential because a diet that is deficient in protein can cause catabolism of muscle as well as adipose tissue. Furthermore, athletes have increased caloric demands compared to the general population, secondary to their increased level of activity. Realistic goals of weight gain should be set, compromising between an athlete's fear of the negative effects of weight gain on performance and the need to prevent serious medical consequences. The athlete may benefit from counseling from coaches, trainers, or a psychologist to help address the underlying causes of her disordered eating.

AMENORRHEA

A frequent consequence of intense physical exercise and low body weight is secondary amenorrhea. This term refers specifically to women who previously had regular menstrual cycles but now have fewer than six cycles per year. Primary amenorrhea, in contrast, refers to women who have never had the onset of menses. The

two most common causes of amenorrhea are pregnancy and menopause. Very thin women and women who exercise regularly can also experience irregular or infrequent menses. Multiple studies have been conducted which demonstrate a relationship between alterations in hormone levels both with inadequate caloric intake and with rigorous physical activity. For example, a study of ovarian function in seventeen runners (20-30 km/week) compared to sedentary controls found that 41% of these athletes with apparently normal cycles were actually anovulatory as measured by hormonal blood levels and ovarian ultrasound.³ Other studies have shown that diets of less than 1000 kcal/day result in abnormal menstrual cycles, anovulation, and decreases in serum concentrations of progesterone, estrogen, FSH, and LH.^{11,12} One hypothesis for why these women become amenorrheic is that a critical level of body fat is required to maintain regular ovulatory menstrual cycles. Other researchers claim that excessive exercise may upset hormonal feedback regulation

Many women may not recognize the potential harmful effects of amenorrhea.

Estrogen deprivation in young women may have effects on bone similar to those that occur in postmenopausal women.



As recently as 1982, exercise-induced secondary amenorrhea was accepted as a "normal" part of high intensity training. "It has also been noted that women athletes in intense training develop either amenorrhea or irregular periods. Studies show this to be of no consequence. Once stressful training is discontinued the menstrual cycle returns to normal and the

woman is able to become pregnant."⁷ Today, however, it is widely accepted that decreases in levels of hormones such as estrogen and progesterone in young active women can have a significant impact on their health. The loss of these hormones can cause physiologic changes in young active women similar to those changes seen in older, postmenopausal women. Estrogen has effects on multiple organ systems. For example, estrogen has been found to increase HDL and decrease LDL cholesterol, thus reducing the risk of coronary artery disease. Furthermore, estrogen acts on the skeleton to inhibit osteoclast resorption of bone and may also stimulate osteoblasts to lay down new bone. Decreases in estrogen levels can result in increased bone loss, whether a woman is twenty-five or sixty-five.

It is important to question a female athlete about her menstrual cycle, especially athletes with eating disorders or a history of stress fractures. Many women may not recognize the potential harmful effects of amenorrhea. Women who report infrequent or irregular menstrual cycles should be referred to their gynecologist for a thorough evaluation. Pregnancy must always be excluded as a cause. Typically a woman will be given oral progesterone to help determine if the amenorrhea is caused by chronic anovulation or from ovarian or pituitary dysfunction. Once the cause of amenorrhea has been elucidated, oral contraceptive pills are often prescribed to regulate the menstrual cycle. This treatment will also provide physiologic levels of estrogen and progesterone.

OSTEOPOROSIS

The third component of the "female athletic triad" is the loss of bone density and resulting osteoporosis in an otherwise healthy but amenorrheic young athlete. Bone is a dynamic organ that is constantly remodeling in response to its environment. Osteoclasts remove bone and osteoblasts form new bone along lines of physical stress. Osteoblasts are stimulated by weight bearing and high levels of

serum calcium, and can be suppressed by malnutrition and corticosteroids. Hyperparathyroidism, hyperthyroidism, estrogen deficiency, and low calcium levels stimulate osteoclast function. Osteoporosis is a reduction in bone mineral density that occurs when the resorption of bone exceeds its formation. Bone density can be quantitated by dual energy x-ray absorptiometry (DXA); a bone density more than 2.5 standard deviations from a determined ideal bone mass is indicative of osteoporosis.⁹ Osteoporosis can be further subdivided into two types. Type I osteoporosis refers to a disproportional loss of trabecular bone which can lead to fractures of the vertebrae and distal radius. Type II osteoporosis affects both cortical and trabecular bone and can lead to hip and pelvic fractures. Type II osteoporosis is considered to be an age-related effect of an increased bone resorption over time, while type I occurs most frequently in postmenopausal women who do not receive hormone replacement therapy.

The highest calcium concentration or bone density typically is achieved by age twenty-five. After this peak, bone density decreases at a rate of approximately 0.3–0.5% per year.⁸ In women, this rate of bone loss increases sharply during the first ten years after menopause, secondary to estrogen deprivation. Estrogen deprivation in young women may have effects on bone similar to those that occur in postmenopausal women. Failure to achieve an adequately high initial peak bone mass as an adolescent can lead to early osteoporosis even without accelerating the normal rate of bone loss associated with aging. For example, one study of forty three female runners (>32 km/wk) found a significant 12 % decrease in the bone mineral density of the lumbar spine in amenorrheic compared to eumenorrheic runners.¹³

In athletes, such as runners, who place high mechanical forces on their bones, a decrease in bone density can result in fractures. Stress fractures were first described in military cadets subjected to the repetitive cyclic stress

of marching. Runners and other athletes also subject themselves to the repetitive stress of their legs pounding against the pavement. Several studies that have addressed the incidence of stress fractures in military have shown the prevalence in women to be between 1.2 to 10 times greater than their male counterparts.¹⁰ GW Barrow et. al found that female distance runners were twelve times as likely as men to suffer stress fractures.² Amenorrheic women with bones that have become osteoporotic are believed to be at increased risk for stress fractures. Other risk factors include extrinsic factors such as an acute increase in training, running surface, level of fitness, and running biomechanics.

Stress fractures often present with localized pain that increases with activity and is relieved with rest. Frequent sites of stress fractures are the tibia, distal fibula, pelvis, femoral neck, and metatarsals. The anterior tibia of a runner may be tender to palpation, while a woman with a femoral neck stress fracture may complain of a nagging discomfort in the groin. X rays may be negative or show evidence of a fracture or callus. Bone scans are a more sensitive diagnostic tool. The treatment includes modification of activities and may require the patient to be non weight-bearing or immobilized in a cast until the pain resolves. Untreated, these may progress to complete fractures. Women with stress fractures of the femoral neck are at risk for hip fracture and avascular necrosis. Non weight-bearing activities, such as swimming or cycling, can be substituted for running while the fracture heals. A great majority of stress fractures are related to overuse and will heal with rest.

It is very important to counsel any athlete with a stress fracture about training modifications, shoe wear, and nutrition. Occasionally stress fractures can represent a clinical manifestation of the female athletic triad of disordered eating, amenorrhea, and osteoporosis. All athletes with a history of stress fractures should increase their calcium intake to 1500 mg per

day in an attempt to increase bone mineralization. The importance of nutritionally oriented diet planning which incorporates protein consumption and adequate caloric intake should be emphasized. Women who are amenorrheic need to be referred to their gynecologist and may benefit from oral contraceptives to increase their levels of estrogen.

CONCLUSION

As women set new records and break old boundaries of athletic competition, the understanding of the orthopedic concerns of the female athlete continues to evolve. Physicians need to be aware of potentially devastating consequences of the triad of disordered eating, amenorrhea, and osteoporosis. Female athletes should be considered to be at high risk for developing these problems. Physicians should have a low threshold of suspicion for stress fractures when evaluating these women for injuries. Furthermore, athletes need to be provided with support and guidance in developing nutritional plans and reasonable training regimens to maximize their athletic performance without compromising their physical well being.

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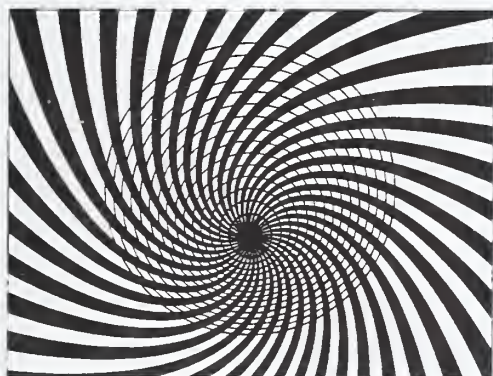
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IMAGES IN MEDICINE

⌘ Scoliosis Due to a Hemivertebra ⌘

Catherine N. Petchprapa, MD, and William W. Mayo-Smith, MD



Figure 1. Computer generated anterior oblique view of the lower lumbar spine and upper pelvis created from axial CT images demonstrates scoliosis and a partially formed vertebra (arrow). The partially formed vertebra (hemivertebra) has led to abnormal longitudinal growth resulting in scoliosis.

Scoliosis (*curvature*, in Greek) is defined as a lateral curvature of the spine. The etiology of scoliosis is usually idiopathic. In rare cases, scoliosis develops due to congenital vertebral anomalies including hemivertebra, as illustrated in this example. Hemivertebra result from a unilateral defect in the formation of the vertebral body. Management of hemivertebra is somewhat unique because treatment can involve removal of the deformed vertebrae in conjunction with spinal fusion.

Though present at birth, congenital scoliosis may clinically manifest later in childhood. The ultimate goal of treatment is to prevent further progression of the curvature. Accurate imaging is important in treatment planning because unlike the idiopathic type, congenital scoliosis responds poorly to orthosis, and often requires spinal fusion to prevent further curvature. Plain radiographs of the spine should be obtained when the scoliosis is initially suspected on the basis of physical exam. Evaluation of complex anomalies is aided by computed tomography (CT), which provides more detailed information (Figures 1 and 2). These three dimensional images were created at a computer workstation using raw data from axial CT scan images. Figure 3 is an example of a normal spine.



Figure 2. The hemivertebra, seen from a more lateral projection (arrow)

Because congenital scoliosis is often associated with anomalies of the spinal cord, spine magnetic resonance imaging may be useful in the workup of these patients.

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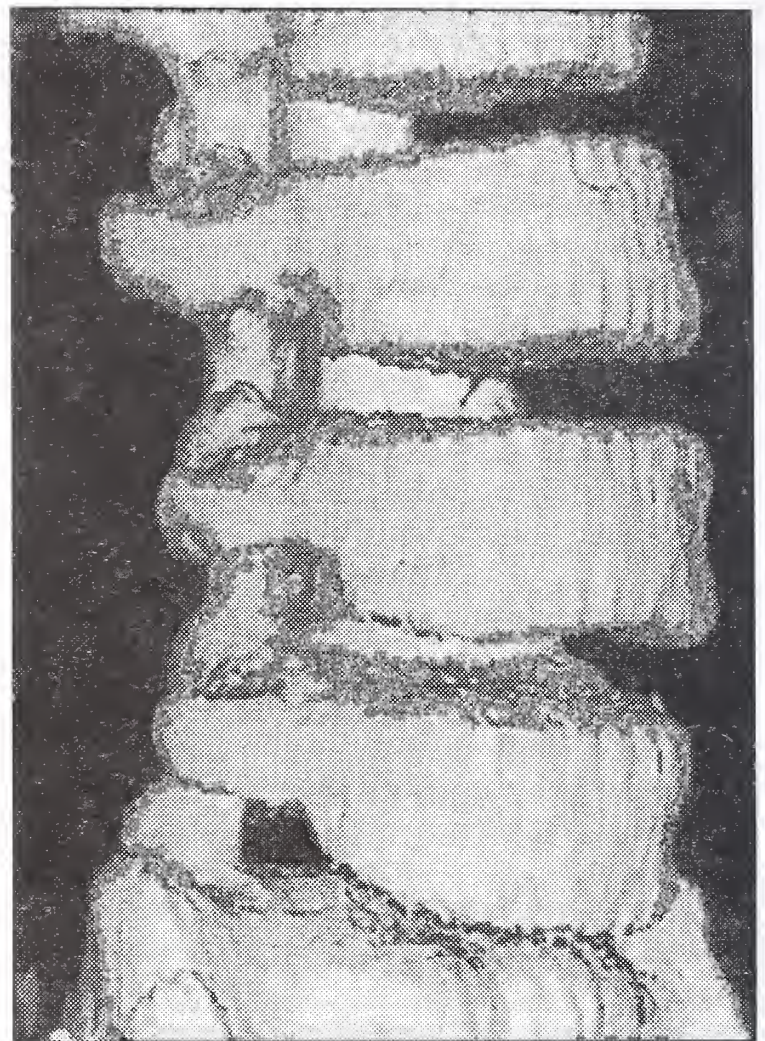
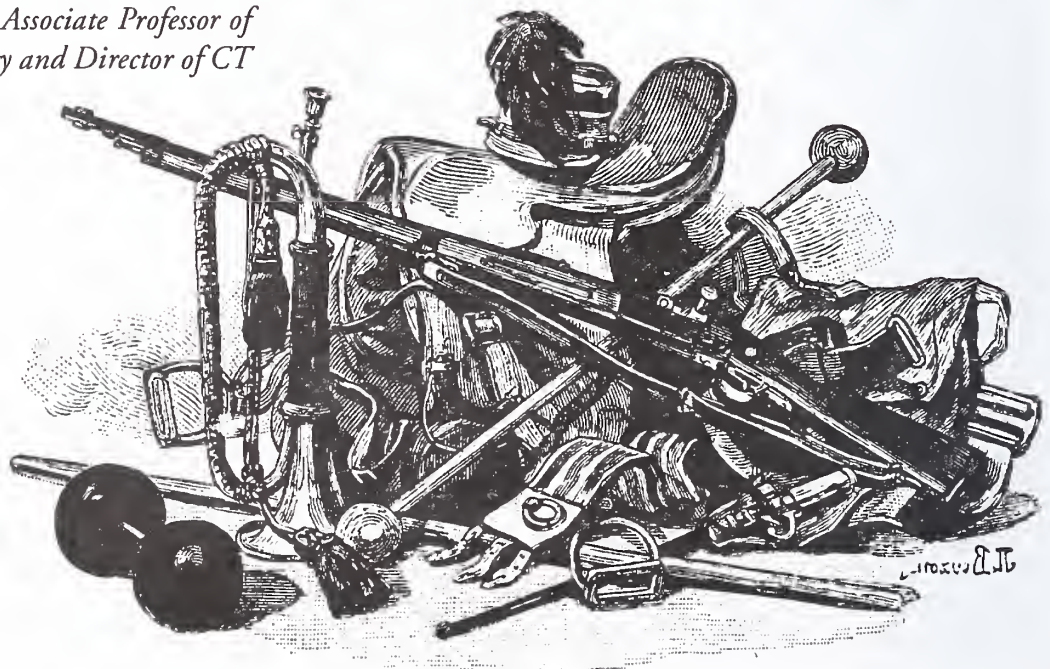


Figure 3. Three dimensional reconstruction of a different patient with a normal spine for comparison.

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Rhode Island Quality Partners, Inc.

The Payment Error Prevention Program

Freda B. Schroeder, ScD

Rhode Island Quality Partners, the Rhode Island Peer Review Organization (PRO), would like all providers in Rhode Island to have a better understanding of the Payment Error Prevention Program (PEPP), a new program requirement for all PROs under the Sixth Scope of Work with the Health Care Financing Administration (HCFA). PEPP is part of the broad Medicare program integrity initiatives under the Clinton Administration. PEPP is designed to reduce payment errors made by Prospective Payment System (PPS) inpatient hospitals using a continuous quality improvement methodology similar to the clinical quality improvement projects implemented by the PROs in their past two Scopes of Work. Although PEPP is a national project, hospitals' participation in PEPP is not voluntary, but is mandatory.

Q: WHAT IS THE GOAL OF PEPP?

In 1998, the Office of Inspector General (OIG) released findings of its audit of the HCFA's 1996 and 1997 financial statements. The OIG estimated that, for each of these years, approximately \$4 billion in erroneous payments were made to hospitals by Medicare.

The goal of PEPP is to protect the integrity of the Part A Medicare Trust Fund. This goal will be accomplished by reducing erroneous overpayments and underpayments made by Medicare for inpatient care provided in PPS hospitals. The purpose of PEPP is to reduce all payment errors, on a statewide basis, and work with hospitals to prevent future payment errors. PEPP will be limited to PPS acute care hospitals and inpatient hospital services; it will not examine physician bills.

PEPP WILL:

- Be used as a surveillance system to measure and track inpatient payment error rates
- Identify causes of inpatient payment errors
- Intervene primarily through educational efforts to reduce future payment errors.

Abbreviations Used:

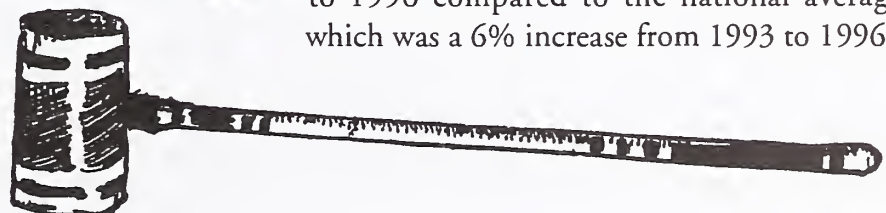
CDAC	Clinical Data Abstraction Center
DRG	Diagnostic Related Group
HCFA	Health Care Financing Administration
OIG	Office of Inspector General
PEPP	Payment Error Prevention Program
PPS	Prospective Payment System
PRO	Peer Review Organization
RIQP	Rhode Island Quality Partners

Q: WHAT ARE THE CAUSES OF THESE PAYMENT ERRORS?

The HCFA believes that the majority of billing errors are not intentional but the result of a very complicated payment system. Many of the errors may be clerical in nature or may result from incomplete documentation or inaccurate coding. The HCFA believes that educational interventions will assist in correcting these errors and that education is at the core of reducing the rate of payment errors.

Aberrant patterns in coding have been a concern to the HCFA. Generally, increases or decreases in the use of certain DRGs by PPS hospitals are expected. However, atypically high billing patterns have been noted on a nationwide basis by the Office of Inspector General (OIG) in studies on certain DRGs from 1993 to 1996 data. For example, in the Executive Summary, the OIG states that "The results of the 1996 validation effort showed approximately 13% of the sample DRG 416 (Septicemia, age 18 or older) discharges should have been coded to a lower weighted DRG. The HCFA estimated that the total overpayment attributable to incorrect DRG 416 classifications was \$ 48,930,882."¹ In another study conducted by the OIG, the study sample of

PPS hospitals had a 73% increase in the use of DRG 014 (Specific Cerebrovascular Disorders Except Transient Ischemic Attack) from 1993 to 1996 compared to the national average, which was a 6% increase from 1993 to 1996.²



Q: HOW WILL THE HOSPITALS BE INVOLVED IN PEPP?

The role of the hospitals in PEPP will be to maintain effective utilization programs, maintain effective quality improvement programs, adhere to coding and billing regulations, and collaborate with the PRO to reduce payment errors. PEPP is not a voluntary program. All PPS hospitals are required to participate in this national initiative. Hospital facilities nationwide will be involved with the implementation of system changes designed to reduce or minimize payment errors.

The PRO is collecting local level data to identify trends and potential opportunities for improvement. Once a potential concern of payment error is identified, the PROs will assist the hospitals with the identification of patterns suggestive of incorrect DRG assignment, medically unnecessary or inappropriate care, inappropriate transfers or premature inpatient discharges resulting in unnecessary readmissions. The PRO will work with hospital providers to identify the causes of payment errors and develop strategies including interventions to reduce the statewide error rate and to reduce future billing errors. The PRO may consult with providers, sponsor small focus groups to communicate coding information relative to problematic areas identified, and publish PEPP information in newsletters. Another educational focus may be medical record documentation, especially for substantiating the principal diagnosis. This will include physician education.

Q: HOW WILL THE PRO ACCOMPLISH ITS WORK IN PEPP?

The HCFA requires that, during the first year of PEPP, the PROs conduct one quality improvement project on unnecessary admissions and one project on DRG miscoding. In addition, a random sample of 1,100 cases per state for FY 1998 was requested by the HCFA's Clinical Data Abstraction Center (CDAC) to establish each states' baseline payment error rate. Starting in February 2000, an additional 93 records per state per month will be

requested by the CDAC, on a random basis, for Medicare discharges occurring on or after October 1, 1999 for a surveillance sample. Of the records the CDAC abstracts, those cases failing screens for medical necessity of admission, quality and DRG coding are forwarded to the PRO along with a 10% sample for quality assurance. The PRO will perform full case review on all records sent by the CDAC.

The PRO will provide the statewide error rate to hospitals when it becomes available. A remeasurement of the payment error rate will be done at a future date to determine if the error rate has diminished. Hospitals will be provided with feedback regarding their specific error rate and level of improvement as data becomes available.

Q: ARE NEW PROCESSES FOR MEDICAL REVIEW IN PLACE FOR PEPP?

Consistent with the existing traditional medical review the PROs have been doing, providers will be notified of any case that cannot be confirmed through medical record documentation as appropriate in the admission, discharge, DRG assignment or where a quality of care issue emerges. Providers will still be entitled to full appeal of any case that is denied. When the review process supports the determination of an inappropriate admission or a change in the DRG, the PRO will notify the provider, the beneficiary and the fiscal intermediary that a payment adjustment must be made. Payment adjustments will be made only on actual cases reviewed by the PRO.

Rhode Island Quality Partners, the Rhode Island Peer Review Organization, is committed to working with individual providers. Would you like to learn more? Call the PEPP team for a presentation. Please contact us @ (860) 632-6347.

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The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.



Multiple Gestation Births in Rhode Island, 1989-1998

Samara I. Viner-Brown, MS, Rachel Cain, and William H. Hollinshead, MD, MPH

Babies born as multiple births (i.e., twins, triplets, and higher order births) are at a higher risk for low birthweight (less than 2,500 grams), prematurity (less than 37 weeks gestation) and infant death (deaths occurring within 364 days of birth) compared with singleton births. Over the past ten years, Rhode Island has experienced an increase in the number and rate of multiple births, a trend that mirrors the rest of the nation.

In 1989, Rhode Island passed legislation requiring public and private insurers to provide coverage for medically necessary infertility diagnosis and treatments, including fertility drug therapies, in vitro fertilizations, and other assisted reproductive technologies. Since then, Rhode Island has seen changes in its birth outcomes including a dramatic increase in multiple births and an increase in the percentage of babies born at low birthweight.

Methods

Birth certificate data for Rhode Island residents were obtained for the years 1989-1998. Infant death data were obtained from a linked birth and infant death database for the years 1992-1998. Data were organized by demographic

factors including, maternal age, marital status, years of education, race/ethnicity and insurance type.

Multiple births are defined as twins and triplets. During 1989-1998, there were no higher order births (quadruplets, etc.). The multiple birth rate is defined as the number of multiple births per 1,000 total live births. The triplet birth rate is defined as the number of triplet births per 100,000 live births. The infant mortality rate is defined as the number of infant deaths per 1,000 live births. All data for the years 1996-1998 are considered provisional.

Results

Between 1989 and 1998, the number of multiple births in Rhode Island rose from 327 births to 500 births, a 53% increase. The rate of multiple births increased more sharply from 22.1 per 1,000 live births to 39.7, an increase of 80%. During this same ten-year period, the number of singleton births declined from 14,441 to 12,098, a 16% decrease.

Specifically, in 1989, 320 twin babies were born (counting only liveborn infants and excluding stillborns in twin births); by 1998, this figure had grown to 463, a 38% increase. Triplets also rose during this period, though more dramatically. In 1989, there were seven triplet babies; by 1998, there were 37, a 429% increase. (Provisional data indicate there were 54 in 1999).

LOW BIRTHWEIGHT

In Rhode Island, between 1989 and 1998, the percentage of all babies born at low birthweights rose from 6.2% to 7.6%. This increase has occurred while other perinatal indicators have been improving, e.g., a decline in the rates of teen births, maternal tobacco use and infant mortality.

In 1989, multiple births represented 2.2% of all births, 16.3% of low birthweight births, and 18.8% of all very low birthweight (less than 1,500 grams) births. Comparatively, in 1998, multiple births represented 4.0% of all births, 31.3% of low birthweight births and 37.8% of

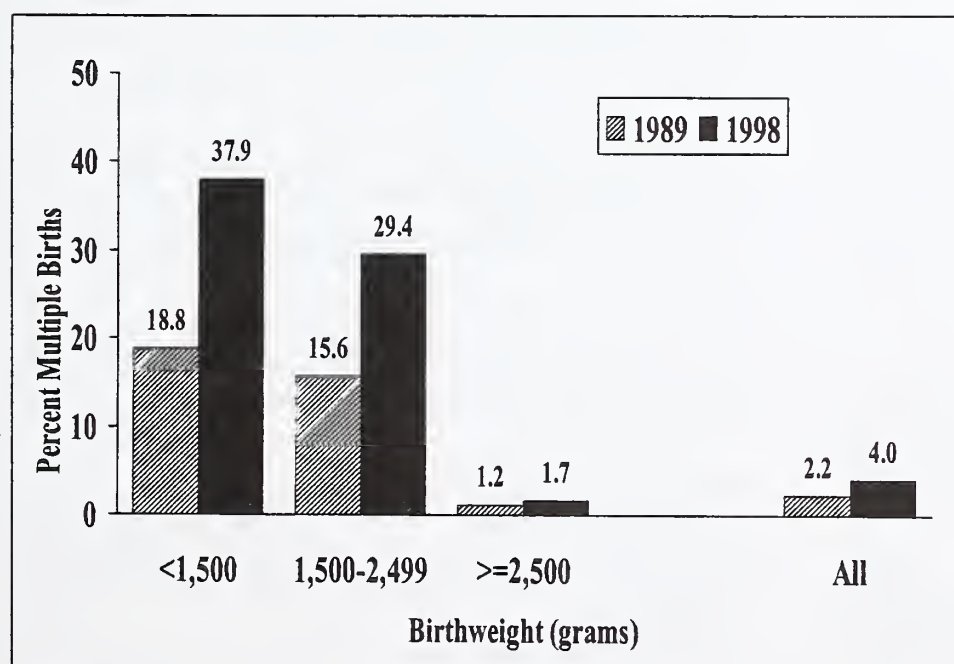


Figure 1. Multiple Births as a Percentage of All Births by Birthweight, Rhode Island, 1989-1998

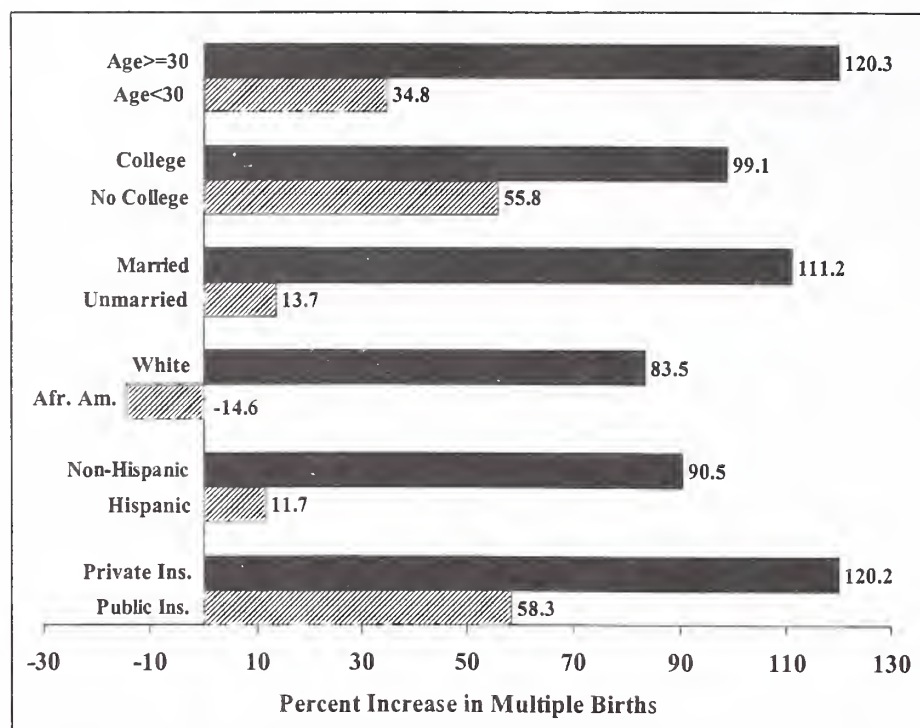


Figure 2. Percent Increase in Multiple Births by Selected Maternal Characteristics, Rhode Island, 1989 – 1998

the very low birthweight births. (Figure 1)

The percentage of multiple births that were low birthweight and very low birthweight has risen during 1989-1998. In 1989, 45.3% of multiple births were low birthweight and 10.4% were very low birthweight compared with 59.8% low birthweight and 16.2% very low birthweight in 1998. There was virtually no change in the proportion of singleton births that were low birthweight or very low birthweight.

PREMATURITY

During the 1989-1998 period, the percentage of babies born prematurely, i.e., prior to 37 weeks gestation, increased from 5.9% to 7.1%. However, the percentage of multiple births born prematurely rose from 22% to 42%. In 1989, multiple births accounted for 8% of all premature births; in 1998, they accounted for 24% of all premature births.

INFANT DEATHS

Infant mortality has declined in Rhode Island over the last decade as it has in the rest of the country. To account for the relatively small numbers of infant deaths in the state each year and the year-to-year fluctuations in the infant mortality rate, data have been analyzed for two five-year periods, 1989-1993 and 1994-1998.

During the period 1989-1993, the infant mortality rate in Rhode Island was 8.0 compared with 6.2 during the 1994-1998 period, a 22.5% decrease. The multiple infant mortality rate decreased by 28% from 46.7 to 33.5.

MATERNAL CHARACTERISTICS

Figure 2 compares the changes in rates of multiple births between 1989 and 1998, by selected maternal characteristics, including age, marital status, education, race/ethnicity, and insurance.

The multiple birth rate approximately doubled among women who were aged 30 or above, college-educated, married, white, or privately insured.

NATIONAL TRENDS

Rhode Island's multiple birth rate of 39.7 is 32% higher than the United States' rate of 30.0.¹ Both the twin and triplet birth rates are higher in Rhode Island than in the United States. In 1998, the twin birth rate in Rhode Island was 36.8 compared with 28.1 in the United States. The triplet birth rate in Rhode Island was 293.7 compared with 193.5 for the country. During the 1989-1998 period, Rhode Island's triplet rate rose 520% compared with 180% for the country.

DISCUSSION

During the ten-year period 1989-1998, the number of multiple births in Rhode Island has risen 53% and the rate of multiple births has risen 80%. This rise in multiple births is of concern because of their higher risk for poor outcomes, including low birthweight, developmental delays and infant death.

Although multiple births represent 4% of all births in Rhode Island, they account for more than one-third of the very low birthweight births and for one in six infant deaths.

Rhode Island's increase in multiple births parallels the country's trend, although Rhode Island's rate of triplet births has risen nearly three times faster.

Between 1989 and 1998, a growing proportion of multiple births were among women who were white, aged 30 or older, married, college-educated and/or privately insured.

Some of the increase in multiple births can be attributed to an increase in the use of fertility drugs and assisted reproductive technologies. The National Center for Health Statistics estimates that about one-third of the increase nationally in triplet births is due to the fact that more older women, who are more likely to have multiple births, are giving birth. About two-thirds of the increase is due to the increasing use of fertility treatments, independent of the mother's age.²

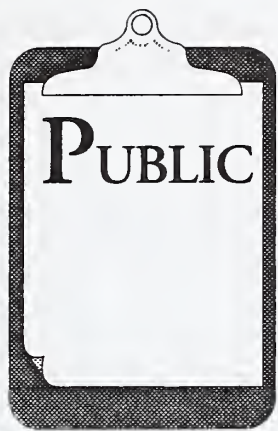
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Public Health Genetics in Rhode Island: First Steps

*Hon Fong L. Mark, PhD, FACMG, Ron Caldarone, MSW, Avery Colt, MA,
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Medical Genetics is maturing at a rapid pace. The way we view medicine and our world, and the ethical, legal, and social implications (ELSI) generated by new genetic technologies are all undergoing radical change. Genetics and genetic testing have entered the realm of big business. The National Institute of Standards and Technology estimates that genetic testing of all varieties is a \$6 billion dollar industry. The Food and Drug Administration's Center for Devices and Radiologic Health lists "genetic diagnostics" as number one on its list of future trends in medical device technology. Educating professionals and the public about the emergence of genetics, and its ethical, legal, and social implications, is of paramount importance. Public health officials, legislators, and others in government also need a solid grounding in the ELSI issues to make constructive policy decisions.

In response, the Rhode Island Department of Health (HEALTH) is educating its staff on the relevance of genetics to traditional public health responsibilities, and is planning for a strong public health presence in the rapidly developing world of medical genetics. HEALTH's long-term goal is to build and support a coordinated, comprehensive, community-based public health genetics program for the State which will:

- * Integrate medical genetics into all relevant public health programs,
- * Involve geneticists, non-geneticists healthcare providers, public health personnel and other professionals, families, parents and other members of the general public as equal partners,
- * Be sensitive to cultural, language, and socioeconomic differences,
- * Evolve in response to the needs of stakeholders and changes in the healthcare environment,
- * Contain quality assurance and quality control surveillance, and
- * Be evaluated to ensure efficiency and effectiveness.

Abbreviations Used:

ELSI	ethical, legal, and social implications
HEALTH	Rhode Island Department of Health
HRSA	Healthcare Resources and Services Administration

In the short term, HEALTH will work to raise awareness and understanding of medical genetics among professionals and members of the general public, and to address relevant issues of concern to physicians, especially those pertaining to the use of genetic tests. Questions about referral, quality control, quality assurance, practice guidelines, and government regulation of these activities will be addressed, as well as ELSI issues relevant to genetics testing.

HEALTH will actively involve diverse members of the public as it proceeds with this work, being especially sensitive to those members of the public who have special needs and who belong to cultural and ethnic minorities. Members of the public will be invited to provide input on all issues relevant to a public health genetics program.

To support its planning activities, HEALTH has received two years of funding from the Healthcare Resources and Services Administration (HRSA) for infrastructure development and planning. Some of this funding will be used to raise awareness and understanding of medical genetics in Rhode Island.



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HEALTH invites the comments, the concerns, the advice - and above all the participation - of physicians as the State takes the first steps in genetics education and planning.

For more information, please contact John Fulton, PhD, Associate Director of RI Department of Health

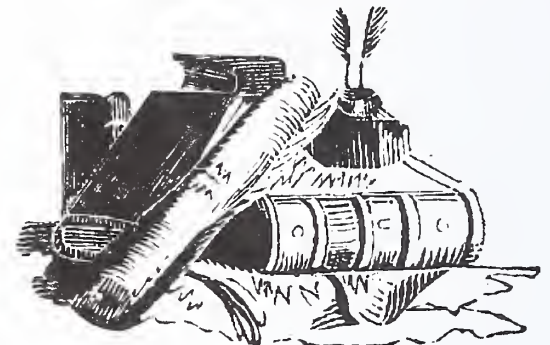
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BOOK REVIEWS



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Reviewed by Sharon L. Marable, MD, MPH

The Guide to Clinical Preventive Services is a reference book on the effectiveness of services such as screening tests, patient education & counseling and immunizations. The second edition of the *Guide*, published in 1997, is an updated version of the original 1989 report of the predominately physician United States Preventive Services Task Force (USPSTF). This latest volume represents the Task Force's critical review of the scientific literature on many preventive interventions, with the Task Force's final recommendation of a test, immunization or counseling intervention only after the Task Force determined that the preventive service is effective based on published clinical research.

The Guide analyzes the scientific evidence for and against over seventy preventive health interventions which include counseling patients on tobacco use, sexually transmitted diseases and unintentional injuries. The Task Force also provides its conclusions on recommended immunizations as well as chemoprophylaxis with aspirin or hormones. Moreover, similar to the first edition, the report includes age-specific charts listing recommended preventive services for patients in various age groups, which primary care physicians may find beneficial.

The chapter discussions of each topic are formatted in terms of: 1) the burden of suffering in the United States from

Abbreviations Used:

USPSTF United States Preventive Services Task Force

the disease 2) assessment of the accuracy of the screening test for a specific disease 3) efficacy of early detection, behavioral risk reduction, chemoprophylaxis, or immunization for a specific condition 4) discussion and the final USPSTF recommendation. Although the final conclusions in this *Guide* are those of the Task Force, each chapter also includes a section with the recommendations from medical societies such as the American College of Obstetricians and Gynecologists, American Academy of Pediatrics, American Academy of Family Physicians, American College of Physicians and the American College of Cardiology. This additional perspective is particularly useful in chapters where the Task Force found insufficient clinical research data to recommend for or against a certain clinical preventive service. Approximately one hundred references are provided at the end of each chapter.

The United States Preventive Services Task Force announced important findings from their extensive review process. First, the Task Force determined that many of the health care problems we see in the office are now more often the consequence of the lifestyle choices made by our individual patients. The Task Force emphasized that the leading causes of death in the U.S., like cancer, cardiovascular disease, cerebrovascular disease, injuries and human immunodeficiency virus infection, are linked to a small number of behaviors which include smoking, physical inactivity, substance abuse, poor dietary choices and failure to use seatbelts. Therefore, the Task Force urges all clinicians to seize every opportunity to deliver a preventive service or message to a patient. Consequently, this updated *Guide* lists patient education strategies and counseling techniques the provider can incorporate

in practice to help patients change behaviors. The Task Force recognized physicians are struggling with providing patients consistent office-based health education and counseling due to reimbursement issues, lack of human resources and lack of time, and the Task Force did not have the authority to address the solutions to these complex issues in the body of this report. However, the Task Force referred the reader to the "Put Prevention into Practice" program administered by the Agency for Healthcare Research and Quality (www.ahrq.gov), and the *Clinician's Handbook of Preventive Services*, for guidance on ways to implement these guidelines. Second, the Task Force concluded that for some health problems, community-based interventions may produce better results than solely delivering the preventive service to an individual in a clinical health care setting. As a result, the government recently commissioned a Task Force on Community Preventive Services, which will develop evidence-based recommendations for preventive services administered within the community. The United States Preventive Services Task Force encourages all clinicians to become involved in community health initiatives and participate in the development public health policy.

The *Guide* has the limitations of any document based on a review of clinical research. For instance, the USPSTF only studied those preventive services performed on asymptomatic persons in clinical venues. Therefore, the Task Force's recommendations do not apply to preventive interventions

provided outside of the clinical setting, such as a community health fair, or to individuals who already have clinical manifestations of the target conditions. Moreover, the recommendations for or against the performance of certain preventive services were based upon the quality of the supporting scientific evidence at the time of publication.

Although this *Guide* was developed specifically for primary care clinicians, physicians with an interest in prevention or evidence-based medicine will also find it to be an essential desk top reference.

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Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report

Provisional Occurrence Data
from the
Division of Vital Records

Underlying Cause of Death	Reporting Period			
	June 1999	12 Months Ending with June 1999		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	227	3,020	305.5	3,673.0
Malignant Neoplasms	183	2,454	248.3	6,811.5
Cerebrovascular Diseases	38	564	57.1	721.0
Injuries (Accident/Suicide/Homicide)	31	372	37.6	6,950.0
COPD	28	496	50.2	437.5

Vital Events	Reporting Period		
	December 1999	12 Months Ending with December 1999	
	Number	Number	Rates
Live Births	1,115	12,918	13.1*
Deaths	956	9,837	10.0*
Infant Deaths	(5)	(87)	6.7#
Neonatal deaths	(5)	(71)	5.5#
Marriages	397	7,757	7.8*
Divorces	302	2,750	2.8*
Induced Terminations	348	4,904	379.6#
Spontaneous Fetal Deaths	33	862	66.7#
Under 20 weeks gestation	(25)	(791)	61.2#
20+ weeks gestation	(8)	(71)	5.5#

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 988,480

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population

Rates per 1,000 live births



Judicial Diagnosis

Medical Records Requests: Doctors, Stop Violating the Law!

Jeffrey Wishik, MD, JD

This column is written in response to what I perceive is a widespread problem in the medical community. Several times in the past few months, new patients have told me they could not arrange for copies of their medical records to be sent to my office. Many people come to me for second opinions. I like to see these records to avoid duplication of testing and to learn about past treatment responses, among other reasons. Furthermore, when I perform medical file reviews and independent medical evaluations, I repeatedly see the consequences when the treating physicians lack this information – inadequate history, duplicate testing, inappropriate treatment, faulty diagnoses, etc.

Physicians' office staff give varied explanations to patients: a policy not to release any records, refusal to send the records because the patient owed the physician money, and insistence that the records could only be released in response to a written request emanating from my office but not directly from the patient. Besides inconveniencing me, the physicians in question are violating state law and Department of Health regulations. Mishandling records requests is a leading source of complaints to the Medical Society and the Board of Medical Licensure and Discipline.

Sometimes I have spoken to the physician and asked why the records were not available. Invariably s/he replies that the patient misunderstood, there is no such policy, and the records will be forwarded. Now I suppose it is possible that the patient did misunderstand though some of the patients who have confronted this problem struck me as quite intelligent and not easily misled. Perhaps some of these physicians are simply dissembling. Or perhaps they don't know what their staff is up to on their behalf. Unfortunately, should there be a formal complaint, the physician will almost certainly be liable for these violations. Indeed, even if the responsible staff member is not a salaried employee, the physician might still be responsible if he or she had control or supervisory power over the individual – the captain of the ship doctrine.¹

The rules regarding records requests are summarized in Sections 11.2 and 12.1 of the *Rules and Regulations for the Licensure and Discipline of Physicians* (R5-37-MD/DO), adopted by the Department of Health in 1967, as amended, January 2000. (These rules, in part, restate Rhode Island

General Law §5-37-22.) It is clear from the statute and rules that the records and medical bills "may be requested by the patient or an authorized representative" [§11.2]. Furthermore, when a transfer of records to another physician is requested in writing by a patient "the original physician shall promptly honor such request" [§12.1.3], presumably within the same thirty days allowed for patient requests as noted in §11.2.

These rules do permit "reimbursement for reasonable expenses ... incurred in connection with copying such medical records" [§12.1.3], subject to a few important exceptions noted below. State law requires the Director of the Department of Health to establish these charges [R.I.G.L. §23-1-48]. There is an explicit fee schedule: 25 cents per page for the first 100 pages, 10 cents per page thereafter; plus a retrieval fee up to \$15 regardless of actual time expended; plus a \$10 special handling fee if records must be provided within 48 hours of the request [§11.2].

Warning - the physician is not permitted to require payment for medical services rendered as a condition for releasing the patient's records. This is explicitly prohibited in §11.2. Furthermore, if the medical records are being requested for purposes of continuity of care the physician cannot require prepayment of the copying and retrieval fee. If a physician is uncertain whether this exception applies, ask where the records are going. When a patient insists on receiving the records, even after you offer to forward them directly to another clinician, you are probably entitled to conclude that the purpose of the request is not continuity of care and therefore you may require payment.

The other main exceptions are more straightforward. You cannot charge for immunization records required for school admission; for records needed to support claims or appeals filed under Social Security or any other need-based federal or state program (e.g. Rite Care, Medical Assistance, temporary disability benefits, unemployment); or for records requested by applicants in connection with Civil Certification Proceedings or Worker's Compensation claims [§11.2].

When a patient requests his or her records, the physician does have the option to "either permit such patient ... to examine and copy the patient's confidential health care

"...if the medical records are being requested for purposes of continuity of care the physician cannot require prepayment of the copying and retrieval fee."



information or provide such patient . . . a summary of such information" [§12.1.4]. In my limited experience, this option seems most popular with psychiatrists and other mental health providers. However, the summary may not solve the problem. Besides creating more work for the physician, the patient has a trump card. If not satisfied with the summary, the patient can still insist on a copy of the entire record, for which the physician shall be paid according to the fee schedule already described.

There is one last subtlety connected to the release of records to the patient, albeit involving unusual circumstances. If the release of records directly to the patient would "in the professional judgment of the physician . . . be injurious to the mental or physical health of the patient . . . the physician is not required to disclose or provide a summary" but should release the records to another physician selected by the patient [§12.1.4]. I have yet to come across such a situation in my own practice. A possible scenario might involve a seriously depressed patient seeking a copy of my cognitive evaluation in which I raise the possibility of a progressive and incurable dementia such as Alzheimer's Disease. Seeing this evaluation might provoke a suicide attempt. I'm sure the reader can think of similar situations. The physician seeking to rely on this narrow exception should be quite sure about the potential for harm, and not use this exception to avoid records release.

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1. This was used frequently in medical malpractice actions. A typical situation might involve a surgeon being held accountable for the independent act of another person in the operating room. The surgeon would be treated as if he were the captain of the ship, and responsible for everything that transpired. Modern cases are moving away from this degree of liability. Unless the surgeon has a major role in training, educating and supervising the other person liability will usually not be found.

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NINETY YEARS AGO

[JUNE, 1910]

D.L. Richardson, MD, Superintendent, gave an update on the Providence City Hospital - initiated by Rhode Island Hospital trustees eager to be "freed from the care of contagious disease, which the Hospital has been treating for 20 years." In February 1906 the City had appointed a planning committee. In June the committee decided to purchase 25 acres between Douglas Avenue and Eaton Street. With a final appropriation of \$425,000, the work started on July 1, 1908. In March 1909 the hospital admitted its first patient. In the 7-building facility, which could accommodate 150 patients, "the lighting is done entirely by electricity." The newly-appointed Hospital Commission planned to build a separate building for tuberculosis patients.

Dr. Charles Chapin, in "Health of Providence," reported that one rabid dog bit 3 persons. All received the Pasteur treatment from Dr. Bowen at Rhode Island Hospital. All survived.

H.G. Partridge, MD, in "Hemorrhage - Antepartum and Intrapartum," reported on 7 cases (two deaths) of premature separation of the placenta and 13 cases (two deaths) of placenta previa at Providence Lying-In Hospital (from 914 deliveries). For the former, he blamed "traumatism and endometriosis;" for the latter, the etiology was "no better known today than 25 years ago."

J.T. Farrell, MD, in "The Incandescent Light as a Therapeutic Agent," praised the efficacy of 50 to 500 hundred candle power. He put "a stout muscular woman of 52" with an injured shoulder under the light for 20 minutes for 4 treatments, at intervals of 3-4 days: she was free of pain for 3 years after treatment. A physician-patient had complained of lumbago attacks each winter. Dr Farrell "begged him to...let me warm his back, which, by the way, was a big one." After 5 treatments, the patient's attacks ceased. A 66 year-old woman with a 20-year history of severe neuralgic pain of face and forehead, who had had her teeth extracted, received 35 minutes of 500 candle power light a few times. She too emerged pain-free.

FIFTY YEARS AGO

[JUNE, 1950]

In "Elaboration in Medicine," the presidential address to the 139th Annual meeting of the RI Medical Society, Peter Pineo Chase, MD, Editor-in-Chief, linked the public's eagerness for government oversight with the rising costs of medicine - but linked those rising costs to physicians' profligate practice patterns. "The principal plea for [bureaucratic control of medicine] seems to be that the increasing cost...is more than we can handle and we will have to let the government pay the bills. I think you are rapidly forcing this result by your extravagant ways, many of which could be easily curtailed." Lamenting "too many" tests, investigative procedures, hormones, intravenous fluids, antibiotics, vitamins, and specialists, Dr. Chase cited Dr. Oliver Wendell Holmes' comment on what he had learned from studying with Louis Pasteur: "I learned not to think that I must give medicine because a patient is sick."

In April 1949 physicians at the Mayo Clinic first reported on the use of cortisone therapy in rheumatoid arthritis. In "Cortisone Therapy in Rheumatoid Arthritis," William J. O'Connell, MD, and Frederic J. Burns, MD, described two cases from the Arthritis Clinic and Medical Services of St. Joseph's Hospital. A 36 year-old woman had had severe rheumatoid arthritis, with a generalized exfoliating psoriasis, for 10 years. In the past three years, she was "...unable to get in and out of bed, unable to comb her hair, brush her teeth or use her arms and hands properly in order to eat." She had been treated with heavy doses of salicylates, gold therapy, and sulphur. X-rays showed fusion of joints. In three weeks, after one intra-gluteal injection (250 mgs), followed by daily 100 mgs injections, she could walk up and down three flights of stairs without pain or fatigue. A 40 year-old married woman, whose disease followed a normal pregnancy and delivery, had the same results. The clinicians "observed no side effects of hyperadrenalism."

R.B. Robins, MD, the past president of the Arkansas Medical Society, speaking at the 139th annual meeting of the Rhode Island Medical Society, declared government insurance unnecessary - proved by Rhode Island's stellar record in voluntary insurance. In 1944, 40% of the state's eligible population was covered by Blue Cross; in 1950, 76.3% was - the highest percentage enrollment in the country. In the next election, physicians could "stop the march of socialism" and "decide whether the American doctor remains free or whether he becomes slave." A Mississippi colleague reworded the 23rd Psalm: "The State is my shepherd: I shall not work."

TWENTY FIVE YEARS AGO

[JUNE, 1975]

In this issue, focused on endometrial cancer, the Rhode Island Division of the American Cancer Society brought together experts in honor of Dr. George W. Waterman. Dr. Waterman, with Dr. Herman C. Pitts, established the Gynecological Tumor Clinic at Rhode Island Hospital, the "first formally structured clinic for this disease in the United States." Arvin S. Glicksman, MD, gave the introductory remarks, noting that the incidence of cervical cancer had been declining for the past 20 years, but that the incidence of endometrial cancer had risen.

Papers included "Cancer of the Endometrium: Progress in understanding the role of hormones will soon make possible selection of patients for hormone treatment;" "Radiation Treatment of Cancer of Endometriosis: Radiation has a place in preoperative treatment and where surgery is contraindicated;" "Medical Management of Cancer of the Endometrium: Medical oncologists must deal with cases not cured by initial therapy and where recurrences are disseminated."

An Editorial described PL 93-641 (National Health Planning and Resources Development Act of 1974), which would unite Comprehensive Health Planning, Regional Medical Programs, and the Hill Burton Act. This law established Statewide Health Coordinating Councils.

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Peer Review: Phony Data, Shoddy Work or Revolutionary Results? “Truth Will Out”

Peer review is one of the cornerstones of scientific endeavor. Reputable journals, where important and even unimportant work is published, all have a mechanism in place for presumably dispassionate, but informed, review of submitted works by at least two volunteer experts. Grants are similarly reviewed by a panel of independent experts, who will meet, periodically, to further evaluate submitted protocols.

The process of peer review works fairly well but not always, for a number of reasons. “Peer” review is not always “fair” review. The evaluators, generally being experts in the field, may pre-judge an author, “I know him. He’s an idiot, so don’t believe anything he writes.” This may be good, for example, if the author is, in fact, an idiot, bad, if the author simply has a running disagreement with the reviewer. Sometimes the editors, who supervise the reviewers, can be bullied. I recall a case where an eminent clinician had a paper rejected by a reputable journal. Not content, like the rest of us, to submit someplace else, he asked for a second set of reviewers. Being eminent, he was appeased. He then got a third set of reviewers before the manuscript was accepted. “A triumph of the peer review system,” he opined, quite ear-

nestly. “You need to be determined and the system will work.” Alternatively, the system caved into an old boy network while maintaining the superficial appearance of propriety.

But what to do when reviewing reports which don’t seem credible? Clinical observations may be incorrect for a large number of reasons and clinical deductions may be wrong for even more reasons. I reviewed a paper (not for this journal) in which a drug reportedly had a salutary effect on a particular group of patients. I had abandoned this drug shortly after it came out because of its severe side effects. All of my colleagues who specialize in my area had the same experience, and now someone claimed the opposite. The submitted report was an open label trial. No double-blind, placebo-controlled trials have been done because no one will do them, the drug being so clearly toxic. There are three possible explanations. One is shoddy data. The investigator used an unskilled person to measure patient outcome and missed the bulk of the problems, or the doctor was himself unable to accurately make measurements. A second explanation is that the results were made up. The author thought one or two patients did OK, so why not invent 30 or 40? Finally, maybe the rest of us are wrong and we all quit too soon. Perhaps a rare patient or two does poorly, but most do well and we all gave up too soon.

Rosalyn Yalow, PhD, won a Nobel Prize for the development of radiommune assays. She developed the technique for quantitating insulin in biological fluids. By this breakthrough she worked out how insulin was secreted and what its kinetics were. Fur-



thermore, her works with S. Berson, MD, allowed measurements on other peptides of great biological import. It was revolutionary. Therefore it was thought wrong and the papers were rejected. When she gave her Nobel Prize acceptance speech, she showed slides of the letters of rejection of her early papers. As a reviewer, can I always tell wheat from chaff, or distinguish stuff that is out of whack because it is wrong from the stuff that is new and different, but right?

Falsified data. Recently a major breast cancer trial reported that bone marrow transplantation was probably a failure, but one center in the trial had remarkable success, so the overall results were not clear. However, the one site was then reviewed and found to have fabricated data. How could someone do this? How could a physician and a scientist destroy all that we hold sacrosanct? For fame? For fear of learning that the original hypothesis was wrong? To self-destruct? To get more grant support? We’ll probably never know, but for me the lesson is, “be careful,” which is why we have the peer review system in the first place.

What should I do with reports that run counter to my own observations? I say to myself, “I don’t believe this,” but if the methodology is sound (short of quality assessment of the person making the measurements) I accept the work. I can never be certain that I am not the biased observer and that perhaps, I am the one who is less astute. I believe that time will tell as more reports are published and more experience is learned and that ultimately “truth will out.”

— Joseph H. Friedman, MD



Great Gods and Little Flies

The common house fly, *Musca domestica*, is about as common as an insect can get. It has cunningly insinuated itself into man's various habitats, from Polynesian thatched huts to glass-walled skyscrapers, adapting itself congenially to every climatic niche, every landscape, every form of domestic structure devised by humans. And like its cousins the locusts, lice and fleas, the ubiquitous fly has been universally rebuked as an annoyance, a menace to health and a grievous burden upon mankind.

For millennia swarms of flies have been viewed as omens of impending pestilence. Accordingly, many cultures had consigned to certain of their gods the responsibility of controlling these disease-associated clusters of flies. This was no menial task to be entrusted to some neophyte god. The fly was a major societal problem which accordingly required a major diety. In Greece, for example, there was Zeus apomyeos, [the god who chases flies], and in Rome, Deus miagros. A god closely associated with the Caananite city of Ekron, Baal by name, was thought by the Philistines to exercise control over their local flies. The Hebrews referred to Baal, disparagingly, as the evil Ba'alzebul or Beelzebub [Hebrew, lord of the flies.] And Matthew, Mark and Luke then identified Beelzebub more precisely as prince of the devils, Satan himself.

It is, in truth, difficult to find kind words for the house fly. One sociologist declared that "they breed from corruption and decay, carry the germs of the foulest diseases." It is said that all living creatures are miracles of divine creation. But why, some wondered, were these relentlessly annoying insects created in the first place? As a punishing plague? As a means of tempering the apostate spirit of man?

Aesop thought flies to be full of empty boasting and vengality. In one fable, the fly sits upon the axle of a racing chariot and exclaims: "See what a dust I do raise!" And in another allegory, the fly demands wages for having merely watched the labor of others.

How dangerous, then, are the flies? Do they deserve the bad press conferred upon them? Are they in the same category as the mosquitoes and lice, major league purveyors of human misery and death?

Flies come in many forms and varieties [indeed, some 2,500 distinguishable species]. Some, the biting species, derive their principal nutrition from the blood of their victims. The non-biting ones [including the common house fly] are more benevolently inclined and get their sustenance from nectar and decaying matter.

The black fly, *Simulium damnosum*, is a tropically-based creature found principally in the rain forests of Africa and Central America. It is the dominant vector for a parasitic disease called onchocerciasis [river blindness.] When a black fly sucks blood from a person afflicted with onchocerciasis, the microscopic blood-borne worms are thus transferred when the fly bites its next victim. The injected worms propagate in the new host, often forming lumpy swellings over the limbs and trunk. But some of these minute parasites also invade the cornea, the outer, transparent covering of the eyeball, resulting in local inflammation and, eventually, scarring. The opaque scars coalesce to cause blindness.

Onchocerciasis, with many millions of victims, is one of the leading causes of blindness in the world today. Another form of communicable blindness, trachoma, is hastened by swarms of house flies which transfer the infective agent of trachoma from one child to the next.

Yet another type of fly [known to crossword puzzle enthusiasts as tse-tse, a Bantu word meaning buzzing insect] is the carrier of trypanosomiasis or African sleeping sickness. Here too, the transmitting mechanism is the bloodsucking tendencies of *Glossina palpalis*, the tse-tse fly.

Kala azar, affecting over 50 million people globally, is passed from person to person by the bite of the sand fly. These three essentially tropical diseases [onchocerciasis, trypanosomiasis and kala azar] result in enormous human suffering and immense economic loss [broad, fertile areas of Africa cannot be agriculturally exploited, almost as though they had been seeded by mine-fields, because of endemic trypanosomiasis. Live stock, too, are severely affected by this parasite.]

The globally distributed house fly, however, does not bite. It is happily sustained by limitless accumulations of exposed food and unprocessed domestic waste and human sewage. It transmits disease organisms first by contaminating its feet with bacterially saturated sewage and then by alighting upon the surface of fresh food about to be consumed by humans. The house fly may therefore transmit such intestinal diseases as dysentery and typhoid. Given the fact that the unsavory diet of the typical fly is human waste, why has not the entire house fly species been wiped out by the germs of typhoid? Actually, the house fly is endowed with a wondrous intestinal tract capable of killing virtually all the bacteria that it consumes. This antibacterial action, however, does not extend to the hairy coverings of its feet; and so bacteria may be disseminated by house flies without hindrance.

In communities with less-than-complete sewage systems, communities that still rely upon outdoor privies or even more primitive fecal-disposal procedures, the swarms of summer flies herald widespread intestinal infections, particularly in young children [the summer diarrheas.] And in tropical communities without sewage systems, diarrhea remains the leading cause of death. Epidemiologists have convincingly demonstrated that the single intervention of encasing windows with screens has substantially reduced the community frequency of diarrheal diseases, the screens creating a barrier between the contaminated flies and the household foods about to be served. Rapid underground movement of household wastes to sewage processing centers represents yet another mechanism keeping flies from contaminated fecal waste. It was no idle claim when a British scientist declared that the greatest single medical advance in the last millennium was the establishment of underground sewage disposal systems.

To those with homes protected by screens, the house fly is little more than a marginal annoyance. But to those whose children are blinded by disease-carrying flies, whose food is covered by swarms of contaminated flies, whose cattle sicken because of fly-borne disease, whose lives are sorely tried, the fly looms as a monstrous obscenity; and how natural then for these oppressed to seek the services of powerful gods such as Beelzebub.

— Stanley M. Aronson, MD

Blood-borne Pathogen Education: Please Pass It On!

"Why do we have to do this anyway?" is a not infrequently heard grumble about the time that Rhode Island physicians prepare to renew their medical licenses. The grumbling refers to the requirement for two hours of CME credits in the area of bloodborne pathogen education necessary for medical licensure in the state of Rhode Island. Although not specifically mandated within the OSHA Bloodborne Pathogen Standard, finalized in 1991, the Rhode Island requirement is clearly consistent with the federal regulation's intent - to reduce transmission of hepatitis B and HIV in the workplace.

There is a certain calculated shrewdness in making blood-borne pathogen education required. Invariably, compliance is markedly higher than with voluntary guidelines. Linking the requirement to medical licensure certainly gets the point across without wasting time or words with the additional benefit of being easily auditable. The ongoing nature of the requirement has another advantage - it functions as a built-in mechanism to disseminate important updates on occupational transmission and postexposure prophylaxis to the relevant target audience.

There are many microbial agents (bacteria, viruses, parasites) which have a blood-borne phase during infection. Why then do we concentrate on hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) for blood-borne pathogen education? The length of time that the microbial pathogen circulates in blood as well as its titer and infectivity (i.e. infectious dose) are the main determinants of the likelihood of transmission following an accidental exposure to blood. The frequency of infection with the specific infectious agent in the population will also affect the dynamics of occupational transmission. Literally, trillions of virions may be found for months to years in the blood of persons chronically infected with

HBV, which partly contributes to the extraordinary propensity for transmission of HBV from minute amounts of blood. In contrast, hepatitis A viremia is short-lived (less than one month), and a few orders of magnitude lower, accounting for the rarity of its transmission by blood exposures.

Even among the "Big Three" bloodborne pathogens, there are significant differences in their propensity for occupational transmission (Table 1). Far and away the greatest likelihood for transmission after a percutaneous exposure from an infected source patient is for HBV. While HBV infection may have the lowest rate of progression to chronic infection compared with that for HIV and HCV, it has the highest risk for death in acute infection and is a leading cause overall for liver transplantation. Of these 3 bloodborne pathogens, hepatitis B is the only one for which a highly effective vaccine exists.

Occupational exposure to HCV is a difficult situation for which there are more questions than answers. HCV infection is more common in the general population than either HBV or HIV, and in high risk groups there are 5-10 times as many HCV infected persons as either HBV or HIV infected. HCV is

not as easily transmissible by blood contact as HBV, with seroprevalence studies of HCWs consistently showing much lower rates of seropositivity for HCV than HBV. This does not constitute grounds for casual dismissal of the issue of occupational HCV transmission as careful postexposure follow-up studies have shown a small but real risk for HCV transmission in occupational settings. Given that reliable postexposure prophylaxis regimens have not been defined, management of an occupational exposure to HCV remains a difficult and challenging problem. The scope of this problem is staggering when viewed through the prism of seroprevalence rates of up to 90% in certain high-risk populations.

Regarding the transmission of HIV in medical settings, the public and lay press have concentrated on the risk for provider to patient transmission. However, the preponderance of evidence is that the risk mainly operates in the reverse direction, i.e. from patient to provider, and this accounts for the greatest proportion of health care worker-related transmission. Extensive lookback investigations undertaken after detection of an infected health care provider have shown the extreme rarity of provider to

Table 1. Comparative aspects of HBV, HCV and HIV with regard to occupational transmission

	HBV	HCV	HIV
Outcome of acute infection			
Resolved	85%	15%	probably 0%
Chronic	15%	85%	100%
Prevalence of chronic infection			
In U.S. population	0.5%	1.8%	0.3%
In high risk groups	1-20%	1-90%	1-20%
Seroconversion risk after percutaneous exposure	6-30%	1.8% (range 0-7%)	0.3%
Postexposure prophylaxis	Yes*	No	Yes*
Vaccine-preventable	Yes	No	No

*Depending on the nature of the exposure.

patient transmission in the United States and western Europe.

While the risk for occupational transmission after a percutaneous exposure to an infected source is lowest for HIV (compared with HBV and HCV), acute HIV infection invariably converts to a chronic infection. Postexposure prophylaxis has been observed to decrease the risk for occupational HIV. However, this intervention probably has a limited "window of opportunity" for implementation to be effective. This requires greater awareness by medical providers, HCWs and others with exposure to blood of what clinical events constitute an "exposure." Appropriate evaluation and intervention mechanisms must be accessible around the clock as well.

So in this era of outcomes analysis, what is the evidence that the federal Bloodborne Pathogen Standard has been effective? This OSHA rule mandated the provision of hepatitis B vaccination by employers for all employees with reasonably anticipated potential for exposure to blood and other infectious body fluids. The institution of this ruling in 1991

produced the sharpest decline in hepatitis B incidence in health care workers (HCWs) since the introduction of the hepatitis B vaccine. Presently, the incidence of hepatitis B infection in HCWs is now less than that in the general population.

Hard evidence for demonstrable outcome benefit of Rhode Island's mandated Bloodborne Pathogen education is harder to come by. Basically the requirement was founded on hope (that education is an effective intervention), fostered by necessity (the 1991 OSHA rule) and implemented with a carrot and stick approach. In all honesty we have no formal assessments of its benefit. But by informal qualitative measures such as numbers of sharps injuries, increased hepatitis B vaccination, improved rates of correctly referred and evaluated employee exposures, efforts seem to be moving in the right direction.

All of the contributors to this issue of *Medicine & Health/Rhode Island* have worked diligently to provide succinct and up-to-date commentary on risks of occupational bloodborne pathogen trans-

mission. These risks are now being recognized as occurring in non-health care related professions as well and a new phase of bloodborne pathogens education will be for us as medical providers to educate those of our friends, family and patients with possible occupational exposure to blood. For all of us, though, the take-home message is the same: (1) protection through vaccination where feasible; (2) exposure prevention whenever possible; and (3) rapid exposure evaluation and intervention when necessary.

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Hepatitis B: The Only Vaccine-Preventable Bloodborne Pathogen

Molly Stenzel, MD

Historically, hepatitis B has been the most prominent infectious bloodborne hazard for health care workers (HCWs). An estimated 100-200 individuals have died annually during the past decade as a consequence of occupationally-acquired hepatitis B infection.¹ Personnel at highest risk are those most frequently exposed to blood and body fluids, including phlebotomists, surgeons, obstetricians, pathologists, and physicians and nurses who work in hemodialysis and oncology units. Over the past two decades, a highly efficacious vaccine has been introduced and policies implemented for the widespread immunization of HCWs. As a result, the incidence of new hepatitis B infections in HCWs has fallen dramatically (Figure 1). However, recent studies have shown that even among those at the highest risk, such as surgeons and phlebotomists, the vaccination rate is only 80%.^{2,3} With diligent adherence to current vaccination policies, occupational hepatitis B infection should become

a thing of the past. Current areas of controversy are the restriction of the practice of HCWs who are chronic hepatitis B carriers, periodic serologic testing to determine long-term response to vaccine, and administration of booster doses of vaccine.

EPIDEMIOLOGY

Within the last 10 years, since the initiation of a widespread vaccination campaign, reported cases of acute hepatitis B in the United States have decreased 50%, from 21,102 cases in 1990 to 10,258 in 1998.⁴ An even more striking decrease in the incidence of infection among HCWs has been noted. In 1993, an estimated 1,450 HCWs were infected, a 90% decrease from the number estimated to have been infected in 1985.⁴ The incidence of new hepatitis B infections in the United States in 1998 was 4 cases per 100,000. In New England this rate was slightly lower than the nationwide average (1.7 cases/100,000 persons).

Abbreviations Used:

CDC	Centers for Disease Control and Prevention
HBIG	hepatitis B immune globulin
HBsAG	hepatitis B surface antigen
HBV	hepatitis B virus
HCW	health care workers
OSHA	Occupational Safety and Health Administration

The public health impact of hepatitis B is due to the effects of chronic infection, cirrhosis and hepatocellular carcinoma. The risk of developing chronic hepatitis B infection is inversely related to the age at which infection is acquired. In the United States (as in Canada, Western Europe, New Zealand, and Australia), most infections are acquired in adulthood. As a result, although approximately 5% of the U.S. population has serologic evidence of infection with the vi-

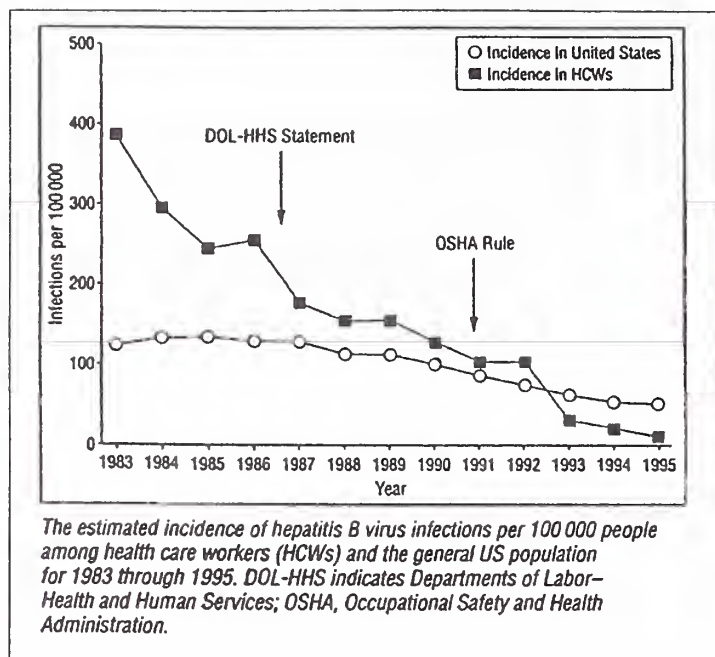


Figure 1 from Reference 2.

rus, only 0.35% is chronically infected. In contrast, in most of the developing world, particularly China, southeast Asia, and sub-Saharan Africa, most infections are acquired perinatally or in early childhood. Consequently, 10-20% of the population in these areas is chronically infected.⁵

CLINICAL DISEASE

The incubation period of HBV is 6 weeks to 6 months. Although most acute infections in adults are asymptomatic, 30-50% of newly infected individuals develop symptoms including nausea, vomiting, anorexia, fatigue, malaise, and jaundice.⁶ Some develop a serum sickness-like syndrome with fevers, skin rashes including urticaria, arthralgias and arthritis. Fulminant hepatitis occurs in less than 1% of acute infections, but carries a mortality of 63-93%.⁶ In most persons, symptoms resolve over 4-12 weeks. Hepatic transaminases may be elevated, even in the absence of symptoms. During this initial phase of infection, patients usually have detectable hepatitis B surface antigen (HBsAg) and hepatitis B core IgM antibody.

Most persons infected with hepatitis B develop an immune response which eradicates infection, with concomitant clearance of HBsAg. In these individuals, subsequent serologic studies reveal HBsAb and HBcAb. Approximately 5-10% of persons infected at an age >5 years old do not eradicate the virus and become chronic carriers⁵; for those infected perinatally the rate of chronic carriage is nearly doubled (10-15%).

Some individuals with chronic hepatitis B remain asymptomatic, able to transmit the virus but without active hepatic inflammation and damage. Others develop

chronic liver disease, culminating in cirrhosis, hepatocellular carcinoma, or both. The risk of these long term sequelae of hepatitis B is greatest in persons who acquire the chronic infection as infants or young children ($\approx 25\%$) as compared to those infected in adulthood ($\approx 15\%$).⁶ In 10-20% of chronically-infected individuals, immune-mediated extrahepatic manifestations occur, including polyarteritis and glomerulonephritis.⁵

Available therapies for treatment include the immunomodulating agent alpha interferon and the antiviral compound lamivudine. With alpha interferon, viral replication is arrested in 25%-40% of treated patients, and 10% of these clear HBsAg six months after beginning therapy. Lamivudine treatment has decreased serum aminotransferase levels and cleared circulating HBeAg but no sustained improvement in chronic liver disease has been seen.⁶

TRANSMISSION

In the United States, the primary route of transmission is parenteral exposure to infected blood. Specific modes that have been identified include sexual contact, both heterosexual and homosexual, injection drug use, occupational exposure, household contact with an acute or chronically infected person, and hemodialysis. Over one-third of individuals with acute hepatitis B have no readily identifiable risk factor.⁷

The most efficient route of transmission is percutaneous exposure to blood, as occurs in needlestick injuries or sharing of needles and syringes among injection drug users. The hepatitis B virus is viable on environmental surfaces for up to 7 days and transmission can occur from inoculation with a blood-contaminated inanimate object. Some nosocomial transmission has occurred in this manner such as within dialysis units and from reusable equipment, such as glucometers.

Perinatal transmission from mother to infant, the most common mode of transmission in the developing world, occurs at the time of delivery by maternal-fetal transfusion and by mucosal exposure to maternal blood in the birth canal. Other body fluids contain virus, though at lower levels than are found in the blood. These include

saliva, semen, vaginal secretions, pleural, pericardial, synovial, and cerebrospinal fluids. Exposure of mucous membranes and non-intact skin to blood or other infected fluids may result in transmission of HBV.

The risk of acquiring HBV infection following a single percutaneous exposure to HBsAg+ blood in a non-immune individual varies from 6% to 30%.⁸ The risk of transmission is directly correlated with the concentration of virus present. In acutely or chronically infected persons, the presence of HBeAg in the blood is a marker for increased infectivity. HBeAg is detectable during active HBV replication and correlates with the presence of approximately 10^8 to 10^9 infectious viral particles per milliliter of serum.⁸

VACCINATION

The most important method for prevention of the transmission of hepatitis B is the vaccination of all susceptible individuals. An effective vaccine has been available since 1981. Vaccination against hepatitis B was originally recommended only for persons at high risk for exposure. Despite the efficacy of the vaccine, the incidence of infection was not significantly lowered during the initial years of vaccine use. In 1991, as part of a national strategy to eliminate transmission of hepatitis B, the Centers for Disease Control and Prevention (CDC) expanded hepatitis B vaccine recommendations to include universal vaccination of newborns and adolescents.⁷ Also in 1991, the Occupational Safety and Health Administration (OSHA) mandated that hepatitis B vaccine be offered to all employees at risk of occupational exposure at no cost to the employee.¹

The vaccines currently in use in the United States consist of recombinant HBsAg and contain no human blood products. The vaccines are well tolerated and safe in pregnant women and in immunocompromised patients. In 1999 formulations of the vaccine without thimerosal as a preservative were approved for licensure, obviating earlier concerns about exposure of newborns to this mercury containing preservative.⁹

SEROLOGIC TESTING

In general, serologic testing to assess for pre-existing immunity prior to vaccinating for hepatitis B is not necessary. The decision to screen prior to immunization is based on cost considerations; serologic testing prior to vaccination may be desirable as a cost-saving measure where there is a high prevalence of preexisting infection. The initial vaccination series induces a protective

TABLE 1 Recommended postexposure prophylaxis for percutaneous or permucosal exposure to hepatitis B virus, United States

Vaccination and anti-body response status of exposed person	Treatment when source is		
	HBsAg* positive	HBsAg negative	Source not tested or status unknown
Unvaccinated	HBIG [†] x 1; initiate HB vaccine series [‡]	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated:			
Known responder [¶]	No treatment	No treatment	No treatment
Known non-responder	HBIG x 2 or HBIG x 1 and initiate revaccination	No treatment	If known high-risk source, treat as if source were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs** 1. If adequate [¶] , no treatment 2. If inadequate [¶] , HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate [¶] , no treatment 2. If inadequate [¶] , initiate revaccination

*Hepatitis B surface antigen.

[†]Hepatitis B immune globulin; dose 0.06 mL/kg intramuscularly.

[‡]Hepatitis B vaccine.

[¶]Responder is defined as a person with adequate levels of serum antibody to hepatitis B surface antigen (i.e., anti-HBs ≥ 10 mIU/mL); inadequate response to vaccination defined as serum anti-HBs < 10 mIU/mL.

**Antibody to hepatitis B surface antigen.

From Reference 1.

antibody response (≥ 10 mIU/mL of HBsAb) in approximately 90% of healthy adult recipients younger than 40 years. Of the remainder, 30-50% will respond after three additional doses of vaccine.¹⁰ Factors associated with decreased response include increased age, smoking, obesity, HIV infection and chronic disease.

For HCWs, serologic testing to confirm adequate response to vaccination is recommended. HBsAb titer should be checked 1-2 months after completion of the 3 dose vaccine series.¹ Those who did not respond should receive a second three-dose series, followed by repeat serologic testing. Health care workers who do not respond to the second series should be counseled regarding ongoing susceptibility to infection, precautions to prevent exposure, and the need for post-exposure prophylaxis following parenteral exposure to potentially infected blood.

Routine booster doses of hepatitis B vaccine are not recommended for those persons who developed a HBsAb antibody titer following the initial vaccine series. Although HBsAb titers decline over time, analysis of a total of 1,786 vaccine recipients monitored for 5 to 11 years showed that while 63 (3.5%) became HBcAb positive (a marker for true infection), none of these individuals had evidence of chronic HBV infection.⁶ Exposure to HBV is thought to induce a vigorous anamnestic HBsAb response that is protective. Therefore, neither routine booster doses of HBV vaccine, nor periodic serologic testing to monitor HBsAb titer, is currently recommended.

In acutely or chronically infected persons, the presence of HBeAg in the blood is a marker for increased infectivity.



Health care workers should keep documentation of vaccination and post-immunization determination of protective antibody titer. Maintenance of such records will help institutions to implement programs of universal vaccination and avoid unnecessary revaccination. If previous immunization and serological response cannot be confirmed, the three-dose vaccination series should be repeated. There is no harm in receiving extra doses of the vaccine.

OTHER PREVENTATIVE MEASURES

In 1987, primarily in response to the burgeoning HIV epidemic, guidelines were issued for the use of universal precautions when handling blood, tissue, and body fluids from all patients. These recommendations emphasize the use of gloves and other barrier precautions—such as gowns and goggles—to prevent mucocutaneous exposure. The guidelines also emphasize the proper use of needles and sharp instruments, including the avoidance of recapping used needles and the disposal of all sharp instruments in designated containers.

When occupational exposure occurs despite these precautions, the need for postexposure prophylaxis is determined by the immunization history and vaccine-response status of the health care worker, and by the HBsAg status of the source patient. Management of the exposure is determined by the assessment of these variables (Table 1). Individuals who have completed the hepatitis B vaccine series and have documented protective antibody need no post-exposure treatment for hepatitis B (assessment for other blood-borne pathogens such as hepatitis C and HIV may be appropriate).¹ If the exposed individual has never been vaccinated, or is known to be a non-responder to the vaccine, and the source patient is known to be HBsAg positive, or considered high risk, hepatitis B immune globulin (HBIG) should be administered as soon as possible, and the vaccination series initiated. Health care workers who have been immunized but whose protective antibody status is unknown should be tested for HBsAb. If adequate antibody is present, no further treatment is needed. If protective antibody levels are not present, and the source patient is HBsAg positive, HBIG should be administered together with a booster dose of vaccine.

TRANSMISSION OF HEPATITIS B FROM HEALTH-CARE WORKER TO PATIENT

Since the early 1970s, at least 375 patients in the United States, Canada, and Europe have acquired HBV infection during invasive procedures performed by 42 infected health care workers.¹ In almost all instances, the infected health care worker was HBeAg positive. Extensive investigation failed to identify breaks in procedure or technique in many of these cases.¹² In 1987, transmission of HIV to patients by a Florida dentist prompted the 1991 publication of CDC recommendations for the prevention of transmission of bloodborne pathogens during exposure-prone invasive procedures.¹³ These guidelines propose that each institution at which invasive procedures are performed (surgical, dental, or medical) identify procedures that are considered "exposure-prone." Examples include digital palpation of a needle tip in a body cavity or the simultaneous presence of the health care worker's fingers and a needle or other sharp instrument in a poorly visualized or highly confined anatomic site. Healthcare workers performing such exposure-prone procedures are recommended to know their HBsAg and HBeAg serostatus, and those who are HBeAg positive should refrain from performing exposure-prone procedures un-

til approved to do so by an expert review panel. The guidelines propose that prospective patients be notified of the health care worker's seropositivity before undergoing exposure-prone invasive procedures. These guidelines stop short of recommending either mandatory HBV testing of health care workers, or absolute restriction of the professional privileges of infected practitioners. The overall risk to patients was not felt to be sufficient to warrant the cost of implementing and enforcing a policy of mandatory testing and modified practice, as exists in Canada and England. Federal law mandates that each state make provisions for the implementation of these guidelines.

CONCLUSION

Hepatitis B is the only one of the currently recognized blood-borne pathogens for which an effective vaccine exists. Continued efforts to promote the vaccination of all health care workers, preferably early in training prior to intensive patient contact, will ultimately result in the eradication of hepatitis B as an occupational hazard.

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Hepatitis C Infection: Opportunity for Exposure in Many Settings

Anne C. Spaulding, MD, Scott Allen, MD, Albert Osei, MD, and Rebecca Ballard, MD

In 1989, a novel bloodborne RNA virus, the hepatitis C virus [HCV], was identified as the agent responsible for most cases of non-A, non-B hepatitis. With subsequent screening of blood donors, transfusion-related hepatitis C (previously 40% of all new hepatitis C infections) markedly decreased.¹ Hepatitis C transmission continues to occur, however, particularly in users of illicit drugs and there is a large reservoir of chronically infected persons from receipt of blood transfusions prior to 1992, when widespread donor screening began. The sequelae of chronic HCV infection can include liver failure and hepatocellular carcinoma, although these occur in a minority.^{2,3} The gravity of these outcomes mandates that prevention needs to be strongly emphasized, especially for work-

ers with occupational exposure to blood.⁴ Traditionally, this would have been defined as health care workers mainly in hospital settings; today these circumstances are being broadened to include public safety workers, staff in substance abuse facilities and medical officers and staff in correctional facilities.

EPIDEMIOLOGY—UNITED STATES AND RHODE ISLAND

HCV is primarily transmitted through percutaneous exposure to blood. The prevalence of HCV infection varies considerably among various populations in the US (Table 1),⁴ being highest in those with repeated blood exposures. Injection drug use now accounts for approximately 60% of HCV transmission in the U.S.

Abbreviations Used:

ALT	alanine aminotransferase
HCV	hepatitis C virus
ISG	immune serum globulin
IVDU	intravenous drug-user
PEP	post-exposure prophylaxis

Many newly diagnosed patients acquired their HCV infection by blood transfusions, mostly predating the serologic testing of blood donors. Although multiple studies have documented very low rates of sexual transmission, up to 20% of persons with acute HCV infection report sexual exposures in the absence of percutaneous exposure. All other exposures (occupational, household,

TABLE 1. Estimated average prevalence of hepatitis C virus (HCV) infection in the United States by various characteristics and estimated prevalence of persons with these characteristics in the population

Characteristic	HCV-infection prevalence		Prevalence of persons with characteristic, %
	%	(range, %)	
Persons with hemophilia treated with products made before 1987	87	(74-90)	<0.01
Injecting-drug users			
current	79	(72-86)	0.5
history of prior use	No Data		5
Persons with abnormal alanine aminotransferase levels	15	(10-18)	5
Chronic hemodialysis patients	10	(0-64)	0.1
Persons with multiple sex partners (lifetime)			
≥50	9	(6-16)	4
10-49	3	(3-4)	22
2-9	2	(1-2)	52
Persons reporting a history of sexually transmitted diseases	6	(1-10)	17
Persons receiving blood transfusions before 1990	6	(5-9)	6
Infants born to infected mothers	5	(0-25)	0.1
Men who have sex with men	4	(2-18)	5
General population	1.8	(1.5-2.3)	NA*
Health-care workers	1	(1-2)	9
Pregnant women	1	—	1.5
Military personnel	0.3	(0.2-0.4)	0.5
Volunteer blood donors	0.16	—	5

*Not applicable.

From Reference 4.

hemodialysis, perinatal) account for about 10% of new cases and no recognizable source for infection is found in 10%. Tattoos and body piercing pose an unknown risk in the United States. Iatrogenic transmission was a tragic outcome of mass parenteral treatment for schistosomiasis in Egypt due to inadequately sterilized equipment. This has resulted in widespread hepatitis B and C transmission in the population and is the largest transmission of blood-borne pathogens in the world.⁵

An estimated 3.9 million Americans are infected with HCV but this is probably a substantial underestimate. Prevalence of HCV in parenteral drug users reaches 80% within the first year and increases up to 86% with time. With the typical IVDU incarcerated more than once a year, approximately 30% of all hepatitis C-infected Americans find themselves in a correctional facility each year, and approximately one third of all prison inmates have antibodies to hepatitis C.⁶ The prevalence of HCV infection in U.S. health care workers is 1-2%, similar to that (1.8%) in the general population.

To date, a systematic seroprevalence study of HCV has not been conducted in Rhode Island. In 1998, when 1,839 new diagnoses of HCV were made locally, 25% were found by testing at substance abuse treatment facilities and 30% at the RI Department of Corrections. The mean age at diagnosis was 41 years. [Linda

Mouradjian, RN, personal communication.] Most cases in Rhode Island are diagnosed in patients age 25-50 years (Figure 1) but this may in part reflect access to testing.

CLINICAL DISEASE SPECTRUM

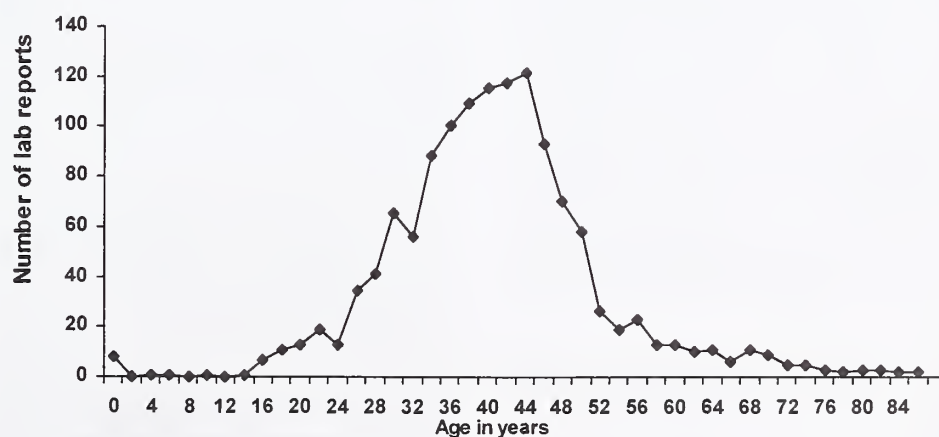
The incubation period of hepatitis C averages about six weeks. Acute infections are largely asymptomatic or have only mild non-specific symptoms. Jaundice is present in less than 25% of cases. The majority (up to 85%) fail to clear the infection and become chronically infected. Most patients with chronic HCV infection are asymptomatic and an incidental laboratory finding of a mild elevation of ALT may provide the only clue to diagnosis. Some form of chronic liver disease develops in 70% but it may often be in

the form of mild fibrosis observed on liver biopsy. Cirrhosis develops in 20% of those with chronic infection, usually over 20-30 years. HCV-related cirrhosis has an annual risk of hepatocellular carcinoma as high as 4% and frequently presents as worsening of previous signs of chronic liver disease. The present understanding of the natural history of HCV infection is that only 15% will acutely clear virus and the majority will remain chronically infected for years.³ Of this latter group, 15-20% will progress to end-stage liver disease (cirrhosis or hepatocellular carcinoma) which is ultimately fatal.⁷ Death with, rather than from, chronic HCV infection occurs in the remainder.⁸

OCCUPATIONAL TRANSMISSION

Occupational transmission of HCV occurs almost exclusively after a percutaneous exposure to blood, such as a needlestick or laceration.⁹ The risk for HCV seroconversion after such an exposure is 1.8%, well below the high risk for hepatitis B transmission (20%) and somewhat above the low risk for HIV (0.03%) by the same route. The risk for transmission following mucous membrane or non-intact skin exposures to blood is unknown; however, blood splashed onto the conjunctivae has resulted in HCV transmission. Simultaneous transmission of HIV and HCV from a single blood exposure has occurred. Specific factors influencing HCV transmission from blood exposures, such as the HCV titer, have not been well delineated.

Figure 1: Laboratory Reports of Hepatitis C by Age at Reporting Date (Rhode Island, 1998)



—Note: Includes unduplicated acute cases, chronic, and resolved cases; and false positive tests; N=1839; single EIA test only. (Courtesy of RIDH)

INTERVENTIONS TO INTERRUPT TRANSMISSION VS. EARLY TREATMENT

Immune serum globulin (ISG) given as immediate post-exposure prophylaxis (PEP) has proven ineffective in preventing establishment of hepatitis C infection.⁴ It is worth noting that ISG produced today has no antibody to HCV since all donors are now screened, making its administration as PEP both pointless and wasteful.

Several case reports suggested that the use of interferon as PEP was beneficial. Theoretically, interferon might be expected to be more effective in treating an established, rather than incubating, infection, and this seems to be borne out in a recent meta-analysis.¹⁰ Currently there are no formal recommendations for prophylaxis following percutaneous exposures to HCV.⁴ Based on the low rate of seroconversion after exposure and the lack of interventions with demonstrable efficacy, the current strategy is to follow exposed health care workers for the detection of HCV RNA or antibody. Infected persons should be referred for consideration of treating early infection. Unresolved issues with this approach include the problems of both false positive and false negative results for both antibody and viral RNA detection, the lack of a prospectively validated evaluation protocol and the cost.⁹

TREATMENT OF ACUTE INFECTION

Because most acute infections with HCV are asymptomatic, there is very little data on which to base decisions regarding treatment in the acute setting.¹¹ Meta-analyses of trials of interferon largely used to treat acute transfusion-related HCV infection suggested that such treatment led to higher rates of resolved infection as assessed by normalization of serum transaminases and clearance of HCV RNA.¹² Whether this viral clearance persists long-term is not known. The role of oral ribavirin added to parenteral interferon in treating acute infection is not known. Interferon as therapy for hepatitis C is currently FDA-approved only for treatment of chronic infection. Current recommendations on post-exposure HCV management point out that acutely infected persons should be referred to specialists who can review the benefits, risks and adverse effects of antiviral therapy with the health care worker.

The chronically infected health care worker

Transmission of HCV from a chronically infected health care worker to patients appears to be extremely low.

An instance of limited transmission of HCV from a surgeon performing cardiothoracic surgery has been noted outside the United States.⁴ Unpublished investigations of other instances of apparent provider to patient transmission strongly implicated shared equipment from injection drug use by the medical provider. Currently in the United States, no restrictions are recommended for chronically HCV-infected health care workers. They should, like all health care workers, pay strict attention to aseptic technique and standard precautions.

An estimated 3.9 million Americans are infected with HCV but this is probably a substantial underestimate.



CONCLUDING REMARKS

Development of an effective vaccine is not likely to occur for many years. An increasingly larger pool of chronically infected persons is being identified as testing becomes more widespread. Thus hepatitis C will continue to pose a risk to health care workers exposed to the blood of HCV-infected patients. No post-exposure prophylactic regimen has been identified which consistently prevents establishment of acute or chronic infection. Close follow-up for 6 months after exposure for early detection of infection is currently recommended. Interferon given at the onset of HCV viremia may prevent establishment of chronic infection but is not currently FDA-approved for this use. Primary prevention strategies are the focus of current educational efforts regarding HCV transmission in the healthcare setting.

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Occupational HIV Exposure

Maria D. Mileno, MD

Healthcare workers are a small but important group at risk for human immunodeficiency virus infection (HIV) as a result of occupational exposure. In the United States, where 8% of the labor force is employed in the healthcare setting, approximately 2 million individuals are at risk for bloodborne exposures.¹ Other groups such as police, firefighters, public safety workers, dentists, dental hygienists and morticians are also recognized as having exposure to blood during the course of their work. An important element of workplace safety is an adequate understanding of what circumstances constitute an exposure in which HIV could be transmitted and what steps to take in post-exposure management. This report answers the most common questions, often asked under pressure, about the occupational risk of acquiring HIV infection.

An upset healthcare worker has sustained a needlestick injury and fearfully asks about occupational exposure to HIV. What do I tell them?

You should focus on the basic message which has 4 main points:

- (1) Not to panic; the risk for HIV transmission is very low.
- (2) They need expeditious and expert evaluation of the exposure to accurately assess the risk, if any, for HIV transmission.
- (3) For some exposures, antiretroviral drugs would be considered or recommended.
- (4) They need medical follow-up for 6 months.

Isn't HIV infection rare in Rhode Island?

Since 1995 there were between 78 and 179 newly reported AIDS cases each year in Rhode Island residents.² These cases represent the "tip of the iceberg" because only AIDS, but not HIV

infection without AIDS, is reportable. Surveillance data indicate that persons of both sexes and all age, racial and ethnic groups have HIV infection in this state. The magnitude of HIV infection in Rhode Island is certainly dwarfed by that in parts of Africa where 25% of the population is HIV-infected; however, it is by no means "rare" for health care or public safety workers to encounter HIV-infected persons in Rhode Island.

How easily is HIV transmitted in an occupational setting?

The risk of HIV infection after a percutaneous exposure to human blood and body fluids is estimated to be 0.3%. This risk depends on several factors.³ The risk is estimated to be highest in cases where the exposure involves a deep parenteral injury with a hollow bore instrument, or in which the source patient has either advanced AIDS or the acute retroviral syndrome, conditions in which the concentration of HIV in blood is very high. The risk from a mucous membrane exposure, such as a blood splash in the eye, is 0.09%. Exposure of non-intact skin to HIV-infected blood has resulted in transmission; the risk for transmission by this route is estimated to be less than that for mucous membrane exposure. Exposures to non-bloody body fluids of HIV-infected individuals, such as urine, tears or feces carry little to no risk.

How many health care workers have acquired HIV infection occupationally?

Nationally 55 persons are confirmed as having seroconverted to HIV after occupational exposure as of June 30, 1999.⁴ Twenty-five of these individuals have progressed to AIDS. The occupations included 23 nurses, 6 physicians, and 19 laboratory workers. Percutaneous injuries accounted for 85% of the exposures. Events leading

Abbreviations Used:

HIV	human immunodeficiency virus
PEP	postexposure prophylaxis
USPHS	United States Public Health Service

to the exposure included 18 unsafe sharps disposals, 4 needle-recapping and 5 episodes of unexpected patient movement during a procedure.

What are the symptoms of acute HIV infection?

The symptoms of acute HIV infection will generally appear within six weeks after an exposure to HIV. They include fever, sore throat, nausea, headache and lymphadenopathy. Persons with possible blood or body fluid exposure to HIV should be advised to seek medical evaluation if these symptoms develop. They should not assume the worst as these symptoms are quite similar to those in other common viral infections such as with mononucleosis due to Epstein-Barr virus.

What data support the use of antiretroviral agents for HIV exposure?

The rationale for postexposure prophylaxis (PEP) is derived from animal studies and from the finding that vertical (mother to infant) transmission can be dramatically reduced by drug administration around childbirth. Limited information on primary HIV infection suggests that use of antiretroviral drugs soon after exposure may theoretically prevent or inhibit systemic infection by limiting the rapid proliferation which otherwise ensues in the initial target cells or lymph nodes of untreated individuals.¹

Does post-exposure prophylaxis prevent transmission of HIV?

In a retrospective, case-control study of 33 seroconverters and 739 exposed but uninfected controls, an 81%

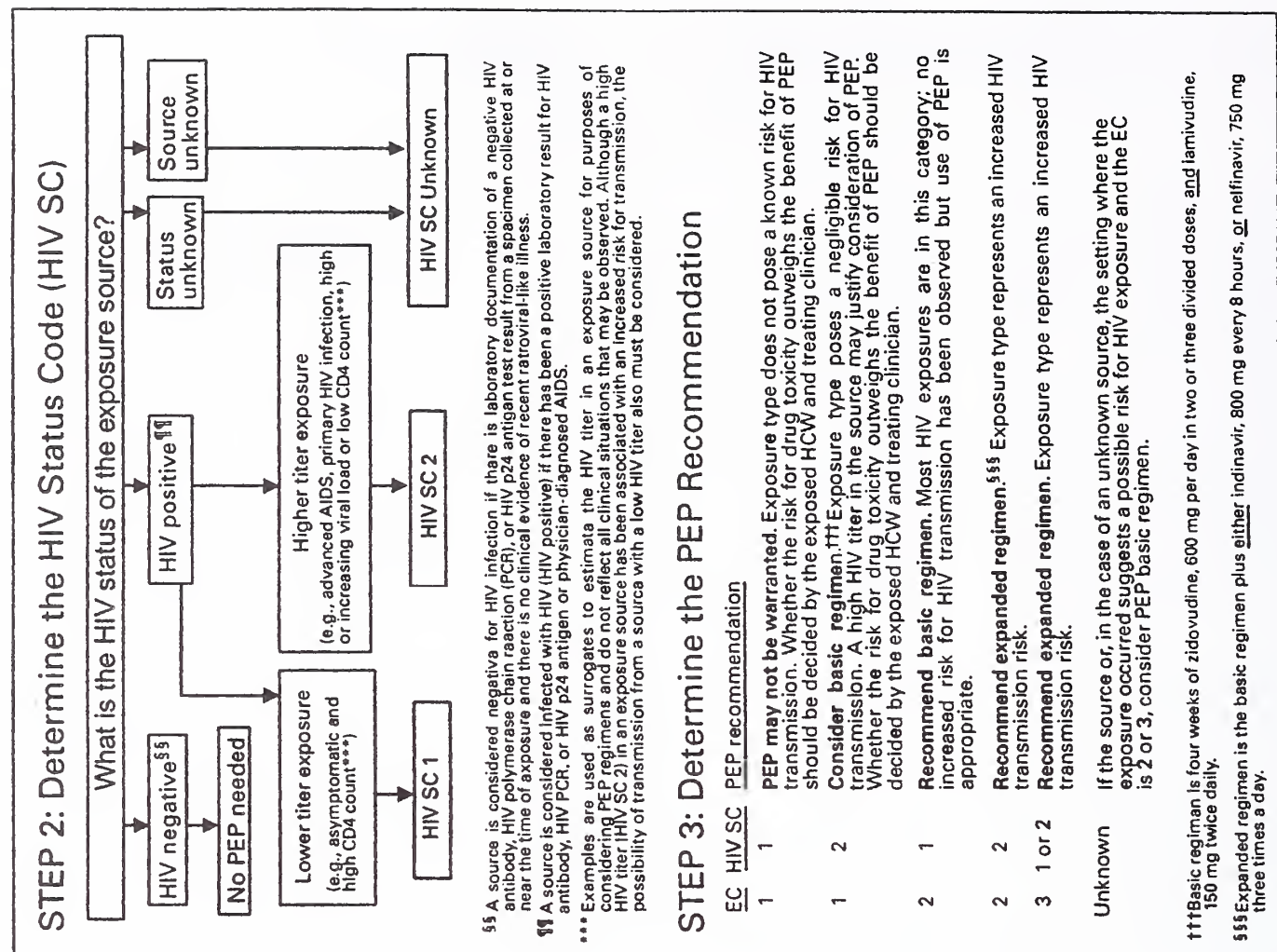
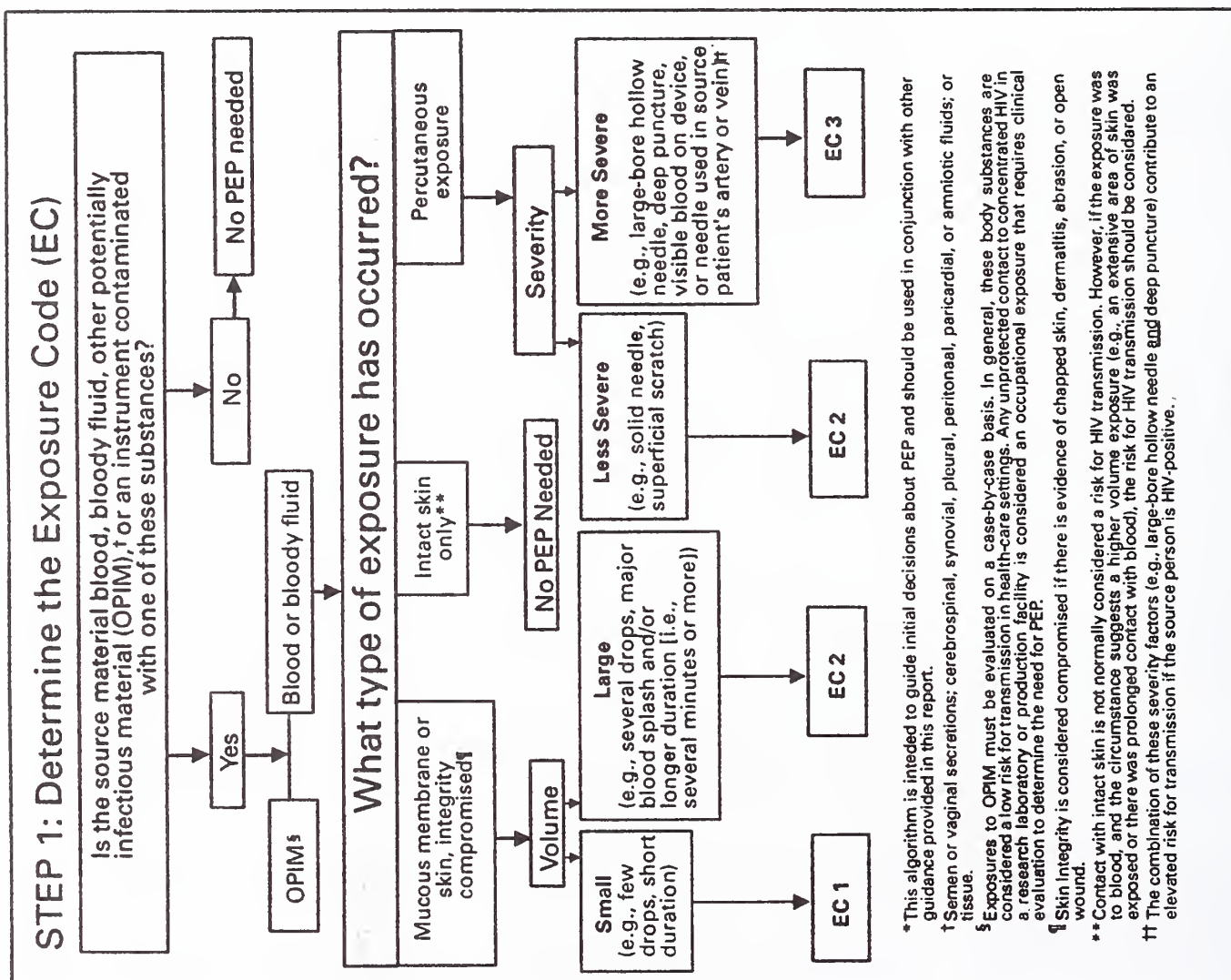


Figure 1. Determining the need for HIV postexposure prophylaxis (PEP) after an occupational exposure. From Centers for Disease Control and Prevention. Public health service guidelines for the management of health-care worker exposures to HIV and recommendations for postexposure prophylaxis. *MMWR* 1998;47(RR-7):1-33.

decrease in the risk of HIV transmission was noted for occupationally exposed healthcare workers who began therapy with zidovudine within 72 hours of the exposure.³ These data largely reflect the use of zidovudine alone soon after or during exposure. The current recommendations,⁵ though empiric, add additional drugs to zidovudine based on the enhanced antiretroviral activity of the combination.

There are reports of failure of PEP in 19 persons. These appear to be due to various aspects including characteristics of the HIV strain (drug resistance, cytologic phenotype), the exposure (high viral inoculum, delayed initiation of PEP) and host factors.

What interventions are available to interrupt transmission? When should they be started?

Initiation of PEP as soon as possible after the exposure is the goal; in practical terms, within a few hours. The current United States Public Health Service (USPHS) guidelines⁵ break the evaluation into 3 steps: first, assess the type of exposure, and second, assess the likelihood that the source patient has HIV infection. The third step is to combine this information into a decision on whether the worker has a high, intermediate, low or no risk to determine the plan for PEP (Figure 1).

Highest risk exposures are percutaneous exposures to a concentrated HIV solution in a research setting, a large volume of blood such as that which can enter a hollow needle, or blood from persons with a high plasma viral load of HIV. These warrant use of a 3 drug regimen (AZT, 3TC and either indinavir or nelfinavir) to interrupt viral replication and viral assembly by several mechanisms of action. PEP is continued for 4 weeks.

For intermediate risks, such as HIV-infected blood spilled on skin which has compromised integrity, a large volume injection of blood from a patient whose HIV status is not known, mucous membrane exposure to blood or blood tinged fluid, PEP should be considered, and a well tolerated two drug regimen of AZT and 3TC can be offered. For low risk sce-

narios, PEP can be offered on a case by case basis depending upon the anxiety of the exposed individual. If there is clearly no risk, such as a splash from a spilled urinal from a person infected with HIV, PEP is not indicated.

Human bites are difficult to categorize with regard to the risk of HIV transmission and there are no formal recommendations on this type of exposure. The presence of blood, whether the skin was broken or a mucous membrane was exposed to blood would need to be considered for any recommendation of PEP.

What about follow-up?

Patients should have baseline and follow-up HIV testing at 6 weeks, 3 months and 6 months. For those taking PEP drugs, appropriate monitoring for drug-related side effects should be in place.⁵ During this time, many persons experience considerable emotional turmoil and referral to the Employee Health Office or designated exposure management specialist can help patients cope adequately with the stress.

What else do I tell a person possibly exposed to HIV?

During this time, the exposed person should take precautions to avoid possible secondary transmission (abstain from sex or use a condom, refrain from open mouth kissing, avoid sharing shaving instruments, refrain from donating blood, organs, or other tissues, and avoid breast feeding or becoming pregnant).^{5,6}

What if the exposed person is pregnant?

There is little information on the safety of the antiviral drugs during pregnancy. Zidovudine use after 14 weeks gestation has not been found to have adverse effects; none of the other drugs have been studied. These medications should be used in pregnancy only if the potential benefits outweigh the risks.

What about medical students on electives or physicians and health workers involved in medical relief efforts overseas?

The prevalence of HIV infection

in many developing countries is higher than that in the United States. Medical students tend not to think of themselves as high risk individuals, and many are unaware of the high HIV endemicity of the areas they visit.^{7,8} Potential risks to medical students overseas include injury from a sharp instrument, mucous membrane exposure, exposure to blood or body fluid following an accident on the road, sexual exposure,⁹ and exposure during medical care involving injections or blood transfusions.

Prior to departure medical students must become familiar with the steps involved in recognition and management of bloodborne pathogen exposure, specifically including HIV. Students should travel with a five-day supply of a three drug regimen (zidovudine, lamivudine, and nelfinavir) sealed in a security wrap. If the packet is not used, it can be recycled for the next student on rotation. If a significant exposure to blood or body fluids occurs, the student should begin the three-drug regimen immediately and return to their medical college for evaluation and possible continued prophylaxis. As much medical history as possible should be obtained on the source patient to assess the risk of HIV infection. A sample of the patient's blood blotted onto filter paper can also be brought back for HIV testing.

What are the limitations of the recommendations for PEP for HIV?

Not every clinical scenario fits neatly into the algorithm for exposure evaluation. For some exposures, e.g. human bites, no data are available on which to base a formal recommendation. Data on efficacy is available only for zidovudine. The addition of other drugs to the regimen is largely empiric and the increasing incidence of new HIV infections with drug-resistant strains is expected to alter future recommendations.

Use of antiretroviral drugs as in PEP is not an FDA-approved medication; USPHS has issued guidelines on their use in this situation.

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Non-Occupational Postexposure HIV Prophylaxis: Clinical Issues and Public Health Questions

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In the years subsequent to the introduction of USPHS guidelines designed to decrease the risk of HIV acquisition in occupational settings, HIV care providers, public health officials and concerned members of diverse at-risk community groups raised the question of whether similar guidelines should be used for the management of non-occupational exposures to HIV.¹ Advocates of the use of nonoccupational post-exposure prophylaxis argue that the level of risk after sexual and injection drug contacts is comparable to that for health care workers who are occupationally exposed. Given that a major public health goal is to limit HIV acquisition among all at risk individuals, then the most appropriate management strategy would be to offer PEP to individuals with a high risk, nonoccupational exposure.

Many pertinent questions have been posed regarding the use of antiretroviral drugs in the nonoccupational setting. Perhaps the availability of such PEP would impair the effectiveness of public health programs de-

signed to decrease HIV risk taking in diverse communities, e.g. among men who have sex with men and injection drug users. Data on the optimal use and efficacy of this prophylactic strategy are limited, and the mainstay of HIV prevention continues to be the promotion of safer sexual practices, sterile needle use, programs to decrease substance abuse, and general HIV risk reduction strategies. The actual experience with nonoccupational PEP has been limited to date, but will be summarized below.

CLINICAL EXPERIENCE WITH NONOCCUPATIONAL PEP

Given the limited data on efficacy, the USPHS has stated that it could not recommend for or against the use of antiretroviral agents after a nonoccupational acute HIV exposure.² At recent U.S. and international conferences on HIV prevention, several groups summarized their clinical experiences offering nonoccupational PEP in a systematic manner. The recipients of nonoccupational PEP have been survivors

Abbreviations Used:

HIV	human immunodeficiency virus
PEP	post-exposure prophylaxis
USPHS	United States Public Health service

of sexual assault, those with volitional sexual exposure, or persons with needle-sharing contact. The duration of therapy and the types of medications utilized have varied from site to site.

The largest clinical series to date has been reported by the San Francisco Department of Public Health in conjunction with the University of California at San Francisco.³ A social marketing campaign targeted primarily at men who had sex with men was developed in the greater Bay area. Over the first year, almost 500 individuals called a hotline which had been widely advertised. The exposures for which PEP was sought included unprotected receptive or insertive anal or vaginal intercourse; mucosal exposure to semen, cervicovaginal secretions or menstrual

blood, or sharing needles. Over 90% had been sexually exposed to HIV, and the vast majority were men who had sex with men. One fifth reported nonconsensual sexual exposure. Participants in the program were assessed for their willingness to adhere to a one month drug regimen, and to participate in a focused, risk reduction counseling program. The standard therapy was AZT and 3TC; approximately 3% also received a protease inhibitor, because of the source being known to have advanced HIV infection, a high viral load, or having had prior antiretroviral treatment. Almost 90% of patients completed a full 4-week course of antiviral medications.

Despite the triage to risk reduction counseling programs, several participants presented for more than one course of nonoccupational PEP. Although no acute HIV infections were recorded within 6 months after the institution of nonoccupational PEP, 5 individuals subsequently became HIV-infected because of continued risk-taking behavior. The San Francisco experience indicates that a subgroup of individuals will engage in ongoing risks despite accessibility to nonoccupational PEP. Public health officials, as well as clinical care providers, need to think about creative ways to maximize the impact of the "educable moment" in order to reinforce the anxiety that individuals have after a high risk exposure, if they present for nonoccupational PEP.

In Boston, the Fenway Community Health Center began a system 2 years ago in which a nurse was available on call, 24 hours a day, to respond to questions related to nonoccupational PEP. To date, more than 100 individuals have contacted the nurse-clinician and almost 90% have received antiretroviral therapy after describing a significant high risk exposure.⁴ The criteria for receiving nonoccupational PEP were similar to those in the San Francisco experience. The majority were men who had sex with men, but almost 10% (primarily women) were survivors of sexual assault. In most cases of sexual exposure, participants reported using alcohol, metamphetamine, or other drugs at the time. Most participants received a 3-

drug regimen (2 nucleoside analogs plus a protease inhibitor) and almost three quarters reported completing the full course of therapy. Drug-related side effects were the main reason for premature discontinuation, particularly diarrhea and malaise. Among patients receiving nonoccupational PEP at Fenway, none have become infected with HIV. Despite referral to trained prevention counselors and other mental health services, 8 individuals have presented for more than one course of prophylaxis.

Similar programs in other locations are examining whether to decrease the length of antiretroviral therapy to as short as one week (University of Southern California program). Other groups, such as one private clinic in New York City, are considering the utilization of the non-nucleoside reverse transcriptase agent, nevirapine, for nonoccupational PEP, given its recently demonstrated efficacy in preventing perinatal transmission when given as two single doses, one to the mother during labor and one to the infant after birth.⁵ Future information regarding nonoccupational PEP regimens will have to be derived from the clinical experiences of centers with the largest experience in this practice.

Even within a state there is substantial diversity to the provision of nonoccupational PEP, at least in part based upon the HIV/AIDS experience of providers at specific sites. A survey of 89 Massachusetts facilities found that in 1998, more than 1,000 patients made requests for nonoccupational PEP in 63 different institutions.⁶ Only 15% of patients actually received nonoccupational PEP, and most of these

were survivors of sexual assault. Most institutions had formal protocols for occupational PEP but not for nonoccupational PEP.

LESSONS FROM OCCUPATIONAL PEP

The key principles of a nonoccupational PEP program are based on the USPHS Guidelines for occupational PEP.⁷ The decision to initiate the use of prophylactic antiretroviral drugs and the specific regimen should be based on knowledge related to the relative risk of transmission, the HIV status of the source, and should integrate information related to the willingness and ability of the exposed person to complete a full regimen. It should also take into account whether the exposure risk is ongoing (e.g. continued drug use). Other factors that need to be considered are presentation within 72 hours of exposure, the willingness of the individual to engage in risk reduction counseling, and the likelihood of adherence to an antiretroviral regimen.

Whether to start with two or three drugs is mainly based on the estimated risk of the exposure for transmission of HIV infection. The risk for HIV infection following occupational percutaneous exposure is 1 in 300.⁸ By comparison, the estimates derived for sexual exposures on a per contact basis are shown in Table 1. The San Francisco program recommends a 2-drug regimen for those anal or vaginal exposures of approximately equivalent risk to that for a percutaneous exposure, e.g. receptive vaginal intercourse. A 3-drug regimen is recommended for higher risk exposures such as receptive anal intercourse or needle sharing with

Table 1. Estimates of Risk of HIV Transmission

Exposure	Risk per episode	Comments
Needle sharing	0.6% to 3.0%	Expert estimates
Percutaneous occupational exposure	0.3% to 0.4%	
Receptive anal intercourse	0.1% to 3.0%	Risks can increase with STDs, higher viral load of source, mucosal trauma, viral subtype
Receptive vaginal intercourse	0.8% to 0.2%	
Insertive anal intercourse	0.03%	
Insertive vaginal intercourse	0.03% to 0.09%	
Receptive fellatio with ejaculation	Unknown	Isolated reports of sero-conversion

From Hirschhorn L, Kunches L, Mayer K. Non-occupational postexposure prophylaxis: Evolving clinical practice. *AIDS Clinical Care* 2000;12:601-2.

an HIV-infected person.¹

The use of antiretroviral drugs for nonoccupational PEP is not FDA-approved, and clinicians should consider obtaining informed consent. High risk exposures to HIV may also entail exposure to other pathogens and clinicians should consider the need for vaccinations, such as for hepatitis A and B and testing for other bloodborne or sexually transmitted diseases.⁹ Pregnancy testing should be considered, as the use of emergency contraception may be indicated for female survivors of sexual assault. If at all possible, the HIV serostatus (serum antibody) of the source of the potential exposure to HIV should be ascertained; if negative, the antiretroviral therapy can be immediately terminated. Testing of semen, if still present in the vagina or anus, for HIV antibody and/or viral sequences, can now be technically accomplished. Presently such testing is not routinely available and should only be done in the context of a forensic investigation. Even then, interpretation of the results is a complex endeavor with both medical and legal implications and should only be undertaken by those with professional expertise in the subject areas.

The most important aspect of the encounter with a patient requesting nonoccupational PEP should be counseling and triage to community-based community risk reduction services. All other forms of follow-up are the same as those for occupational PEP. These include making the patient aware of the symptoms of acute HIV infection and the need for immediate clinical evaluation in that setting, and laboratory testing to monitor for drug toxicity and follow-up HIV serologies.

RISKS AND COSTS OF NONOCCUPATIONAL PEP

A concern by public health officials is whether the availability of nonoccupational PEP may lead to increased HIV risk-taking behaviors, because of a false sense of security provided by this "chemical condom." Recent outbreaks of gonorrhea and syphilis have been reported among men who have sex with men in San Francisco, Los Angeles, New York and now Boston, suggesting a failure of community norms around safer sexual practices. On the other hand, providers

who have prescribed nonoccupational PEP in San Francisco, Boston and other locations have noted the willingness of some individuals who "dodged the bullet" to undergo ongoing risk reduction counseling. The net effect of the availability of nonoccupational PEP in relation to HIV spread remains to be determined.

The use of antiretroviral drugs for nonoccupational PEP is not FDA-approved, and clinicians should consider obtaining informed consent.



Another concern is the intermittent use of antiretroviral drugs by uninfected people and its potential contribution to antiretroviral resistance. In one scenario, an individual exposed to a partner taking combination antiretroviral therapy could result in the transmission of resistant virus if the PEP regimen is ineffective against the source's resistant virus. The person who failed PEP could be infected with an HIV isolate which has evolved multiple drug resistance further complicating their treatment. Another concern is that if an individual unknowingly became HIV-infected and used antiretroviral drugs intermittently for nonoccupational PEP in the mistaken belief that they afforded protection against HIV transmission, this individual would be more likely to develop multiresistant virus over time.

The last concern regarding PEP is the question of who should pay for these medications. Because of the lack of definitive clinical trial data, these medications are not approved for nonoccupational PEP and some third party payers may not cover the cost. The estimated cost of a 28-day course of dual nucleoside therapy is approximately \$500; this is doubled with the addition of a third drug. Appropriate laboratory monitoring adds another \$500. In some jurisdictions, structured public health programs have borne at least the drug costs because of the potential benefit for near-term prevention of

HIV infection and long term reduction of HIV risk taking behaviors. Other public health officials view the significant cost per individual for nonoccupational PEP, the relatively low risk of HIV transmission in untreated individuals, and the lack of definitive efficacy data as compelling reasons not to support the cost of such programs. In many settings, the costs are paid by the individual patient.

FUTURE OF NONOCCUPATIONAL PEP

The Centers for Disease Control has established a national surveillance system, the HIV Nonoccupational PEP Registry, whose goal is to provide a simple system for providers to contribute anonymous data on reported exposures and rates of new infections, in patients who receive prophylaxis compared to those who do not. The Registry is tracking drug regimens, duration, toxicities, rates of adherence, and other health consequences of nonoccupational PEP in diverse communities. Interested providers can provide information for the PEP Registry by logging on to the Web at www.hivpepregistry.org, or by calling 1-877-HIV1PEP (1-877-488-1737). The CDC provides a \$10 stipend for each baseline or follow-up report.

The CDC is also supporting other kinds of surveillance activities, including a 6-site surveillance network in Massachusetts, tracking the utilization of nonoccupational PEP in diverse locations.

HIV transmission continues to be a major public health problem, as advances in antiretroviral therapy extend people's lives, but do not eradicate the virus. Many strategies have to be developed to curtail the epidemic, including more focused and culturally-specific risk reduction programs, and the development of safe and effective vaccines and topical microbicides. While the use of antiretroviral drugs to prevent HIV transmission is supported by animal and epidemiological data, the public health effectiveness of this intervention needs to be monitored on an ongoing basis in order to compare its relative utility to that of other prevention interventions.

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Accidental Blood Exposures: A Frontline Perspective

Jane Ellen Cassidy, RN, COHN-S

It is mid-morning and the phone rings in the Employee Health Office (EHO). A clinical nurse manager calls that a nursing assistant has had an accidental needlestick. Shortly thereafter this frightened health care worker enters the office, setting our postexposure evaluation process in motion. On paper the description of an exposure evaluation looks technical and bureaucratic; in reality it is often a tense and dramatic interaction.

As an Employee Health Nurse and certified HIV Counselor, I have developed a frontline perspective from my experience evaluating health care workers who have sustained accidental blood and body fluid exposures. Concerns about hepatitis B transmission have gradually receded due to widespread vaccination of HCWs. Most vaccinated individuals consider themselves protected and regard management of this part of an exposure as a small annoyance in the need for a

booster dose of hepatitis B vaccine. Views on hepatitis C risk from a blood exposure are mixed but muted, mainly because of the perception that most of the disease from hepatitis C is asymptomatic. Far and away the most dominant concern in the interaction centers around the potential for transmission of HIV.

The range of emotions felt by a HCW following an occupational exposure runs the gamut from terror and panic to anger and denial. The Counselor must recognize these emotions and respond in a manner that helps the HCW constructively deal with them while at the same time accomplishing the necessary medical evaluation and interventions.

The frank terror of an exposed HCW can hamper successful counseling. One simply cannot ignore this and proceed to explain the intellectual facts of the risk factors from this particular exposure for transmission of

Abbreviations Used:

EHO	Employee Health Office
HCW	health care worker

bloodborne viruses. It is often best to "grab the bull by the horns" and get the HCW to admit fear as this step enables him/her to regain composure. Self control is virtually a prerequisite to the difficult process of fully informed consent. The HCW's concerns and anxiety cannot be fully allayed in one interaction and reassuring the employee of my continued availability just to talk things over has been enormously helpful. I also make the specific point that I will promptly provide all laboratory results with a detailed explanation and that all such results are held as confidential information in the EHO.

Panic in the face of an exposure can result in great difficulty in securing correct and complete details of the

incident. The HCW needs to be seen in a quiet and private location to ensure uninterrupted counseling, realistic discussion and compassionate reassurance. Attention to this detail alone often helps to decrease the level of anxiety. While the information provided by a highly competent counselor must be scientifically accurate and contain current facts and recommendations, it must be presented with concern and compassion. There is clearly a limit to how much information an individual can absorb in an acute situation and provision of both written material and formal opportunities for follow-up discussion should be part of the exposure evaluation plan.

On occasion a HCW may not report a significant blood or body fluid exposure. Such denial can completely jeopardize the care and well being of any employee. Sometimes the notification of the incident to the appropriate counselor occurs long after the time period for effect postexposure interventions has elapsed. Perhaps a co-worker or supervisor alerts the EHO and a great deal of effort is then undertaken by the counselor who now must work the exposure evaluation process through in a reverse manner. Surprisingly, the individuals in denial span the range from unskilled laborer to highly educated professionals, including physicians.

Substantial efforts continue to be underway in most hospitals to remove ignorance as an explanation for why some bloodborne pathogen exposures are never reported. At Memorial Hospital, we have an ongoing education program in which all hospital staff receive annual training about standard precautions, the bloodborne pathogen standard, and the appropriate actions to be taken should an exposure occur. This has included using educational materials translated into other languages. Each employee must satisfactorily complete the subsequent exam.

Anger rages in HCWs when they have sustained an exposure due to someone else's carelessness. Sharps left at the bedside, on procedure trays, inappropriate disposal in trash or linen,

and overfilled sharps containers have been among the causes. These HCWs may have difficulty getting beyond their anger and their focus on finding who is to blame. Before attempting to complete the exposure evaluation, I must first work with the HCW to defuse this anger. This is often quite difficult as it entails making them stop looking for missing pieces of information and getting them to focus their attention on dealing with the evaluation and interventions, as appropriate to the particular exposure.

The frank terror of an exposed HCW can hamper successful counseling.



An exposure counselor must be prepared to deal with the possibility that a HCW could have a positive HIV serology, either at baseline (indicating prior infection) or on follow-up testing (indicating occupational transmission). Discussions of these possibilities in the initial interview greatly impact the interaction with the HCW. The HCW must be educated to appreciate the advances in medical treatment today for HIV-positive patients. Demonstration that an adequate plan of action has been developed and anticipation of questions concerning quality of life, ability to work, available health care and risk to others can greatly assist the HCW in gaining emotional mastery over this aspect of an exposure evaluation. In addition, having a well thought-out plan in advance for dealing with occupational HIV transmission benefits the exposure counselor as well by providing a professional roadmap to ensure that the best possible medical care and legal protections are afforded the HCW.

SUMMARY

The emotional impact of a blood or body fluid exposure on a HCW is substantial and can affect the HCW's emotional outlook, both personally and professionally. Qualified counselors must be adept at recognizing a variety of emotional responses and should be prepared to individualize their interactions with HCWs in order to get them to direct their immediate attention on the details of the post-exposure evaluation. Effective counseling and compassionate support go hand in hand with vaccines and medications to help HCWs following these frequently traumatic incidents.

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Sample Cases of Exposure

Michael G. Tauber, JD, and Brent R. Canning, JD

A nurse in your office is drawing blood for routine tests on John Doe, a new patient. Unfortunately, after drawing the blood, the nurse pricks her finger with the needle. You are aware that the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens Standard requires that you provide for a post-exposure medical evaluation of your nurse. But what if John Doe refuses to consent to having his blood tested? Can you test his blood without consent? Can you disclose the results to your nurse? Can you disclose the results to the health care provider providing the post-exposure evaluation to your nurse?

As an employer, every physician is obligated by the federal OSHA regulations to document the identity of the source individual, if known (John Doe, in this case), unless the physician can establish that identification is not feasible or is prohibited by state law. OSHA regulations also require that, after consent is obtained, the source individual's blood be tested, as soon as possible, to determine whether the source individual is infected by the human immunodeficiency virus (HIV) or the hepatitis B virus (HBV). Finally, the regulations require that the results of this testing be provided to the exposed employee and to the health care professional evaluating the employee. This is what the federal regulations require. But what is the impact of Rhode Island law on the situation?

At the outset, in the context of a physician's office, the actual identity of the source individual will almost always be known. Under Rhode Island law, of course, consent is generally required to draw blood for testing, and to disclose the test results. There are, however, exceptions for HIV testing if a physician's employee is exposed to blood or other bodily fluids. Rhode Island law permits testing and appropriate disclosure of the test results, *without consent*, when there has been a significant percutaneous or mucous membrane exposure to blood or bodily fluids of a type and in sufficient concentration to permit the transmission of HIV. In order for the testing to be permitted the exposed employee must document the time, place, and nature of the exposure. The employee must then document, within forty-eight hours of the exposure, the names of: 1) the people exposed; 2) the source individual(s); and 3) any witnesses to the exposure. Finally, the exposed employee must submit to a baseline HIV test that yields a negative result.

Alternatively, a blood sample that has already been drawn may be tested for HIV, *even if consent is refused*, if a health care provider in a private physician's office is determined by a so-called exposure evaluation group to have had significant exposure to the blood or bodily fluids of a patient, and the exposed person undergoes a baseline HIV test. [In the case of a private physician's office, an exposure evaluation group consists of three impartial physicians, who were not directly involved in the exposure incident, who are designated to determine whether the exposed employee was, in fact, involved in a significant exposure incident.]

Unfortunately, there are no corresponding exceptions un-

der Rhode Island law for HBV testing. Therefore, it would, likely, be contrary to

Abbreviations Used:

HBV	hepatitis B virus
HIV	human immunodeficiency virus
OSHA	Occupational Safety and Health Administration

the letter of the law to disclose the results of an HBV test without the patient's consent. As a practical matter, however, it is not clear that a court or the regulatory authorities would find a violation in the limited circumstances of a pre-existing blood sample being tested and the results being disclosed only to the exposed employee and to the health care provider responsible for the employee's post-exposure evaluation and treatment. In balancing the exposed individual's need for the HBV test results against the source individual's privacy, a tribunal might very well determine that the need outweighed the minimal additional intrusion into the privacy of the source individual caused by the HBV testing. The fact that the General Assembly has explicitly provided for the nonconsensual notification of other health care providers (specifically, emergency medical technicians) who are exposed to infectious diseases might also influence the tribunal's view.

From a liability point of view, the least risky approach is to obtain a court order for the HIV and HBV testing. This is more expensive and time-consuming, but it does avoid the issue of the source individual's consent. Obtaining a court order is also the only option if a pre-existing blood sample does not exist.

The police bring a person to you whom they have arrested for sexual assault. The victim has asked the police whether the suspect is HIV+ and they have brought him to you for testing. The suspect refuses to consent to the blood test but the police order you to perform it any way. What should you do?

Whenever a patient is brought to a health care professional, the health care provider's primary duty is to the patient, not to law enforcement officers. The interests of the patient should control any treatment or testing decisions. Unless authorized by a search warrant or court order, law enforcement officers may only request, not insist, that a patient submit to a blood test. Health care providers are under no obligation to draw blood specimens simply at the request of law enforcement officers. The performance of blood tests should be dictated by the medical or surgical needs of the patient, not the police.

A search warrant is a document that authorizes *law enforcement officers* to search for and seize evidence. Search warrants may be drafted to authorize the withdrawal of a blood sample. Health care providers are not obligated to assist police in carrying out a search warrant by drawing blood. Refusing to draw blood is not an obstruction of justice.

Practically speaking, however, a health care provider who draws a blood sample at the request of law enforcement officers and pursuant to a search warrant, but against the wishes of the patient, will most likely be protected from any claim of civil

liability brought by the patient, so long as the sample was drawn in a competent and reasonable manner. Nevertheless, if the patient refuses to consent, the safer practice is to respect the patient's wishes, document the refusal, and advise the police of your position.

Alternatively, law enforcement officers may obtain a court order that specifically directs a health care provider to draw a blood sample. Unlike a search warrant, a court order is directed to the health care professional, ordering compliance with the court's instructions. A health care provider should comply with such an order even if the patient refuses consent. A health care provider could be held in contempt for failing to comply with a court order, which could mean a fine or imprisonment. Again, the blood-drawing procedure must be performed in a professionally competent manner.

As is often true with legal issues, however, it is important to distinguish different factual circumstances. In this case, it is important to differentiate between situations in which the police merely suspect that a person has committed a crime (regardless of the strength or reasonableness of the suspicion) and those in which a person has actually been convicted of a crime. Under Rhode Island law, people actually convicted of certain crimes are to be tested for HIV regardless of whether they consent. Among the crimes that trigger this requirement are possession of a hypodermic needle associated with intravenous drug use, prostitution, and sexual assault involving sexual penetration. Of course, it is

Unless authorized by a search warrant or court order, law enforcement officers may only request, not insist, that a patient submit to a blood test.



closure of the test results without an individual's consent creates some legal exposure for health care providers. Although the risks may be minimal, they are risks nonetheless, and the costs of defending a civil suit, in time, if not financial and emotional expense, warrant caution.

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Rhode Island's Syringe Exchange Program (ENCORE)



E. Timothy Latta, MPH

From 1983 to 1999, 749 of the 1,968 total AIDS cases diagnosed in Rhode Island (38%) identified injecting drug use (IDU) as their primary risk factor for the disease. This makes IDU the most significant risk factor for AIDS in Rhode Island residents, exceeding men who have sex with men (MSM) and more than doubling the number of cases attributed to heterosexual sex. Rhode Island's overall rate of AIDS cases with a primary risk factor of IDU has been substantially higher than the national figure for many years. (Figure 1)

In response to this escalating problem, Rhode Island initiated a comprehensive program that incorporates education, needle exchange, counseling, outreach, and referrals (ENCORE) for injecting drug users in the state. Estab-

lished in April 1995, ENCORE is a Rhode Island Department of Health program administered by the Office of HIV & AIDS and coordinated by AIDS Care Ocean State. ENCORE was established to reduce the syringe sharing and other high-risk behaviors that place injection drug users and their sexual partners at risk of contracting blood-borne diseases.

The ENCORE program is a "one-for-one plus one" exchange; individuals must have a syringe to exchange for a new syringe. All enrollees are given a pre-enrollment interview for evaluation purposes. At these interviews, information on risk factors is collected. In order to protect client confidentiality, each par-

Abbreviations Used:

CDC	Centers for Disease Control and Prevention
ENCORE	education, needle exchange, counseling, outreach, and referrals
IDU	injecting drug use
MSM	men who have sex with men

ticipant is assigned a unique client code during the initial enrollment.

While needle exchange programs have traditionally encountered significant opposition, strong support by the public health and medical communities for these programs has been well documented. Research has shown that IDUs using syringes obtained from needle exchange programs have lower rates of HIV incidence compared to IDUs using syringes obtained

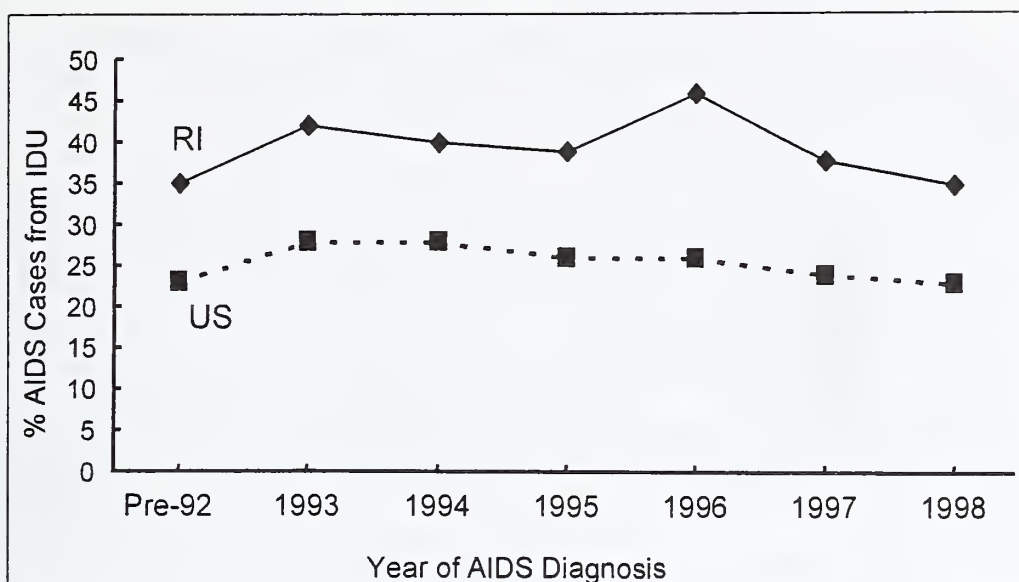


Fig 1: Percentage of AIDS cases attributed to IDU, RI vs. US, 1983-1998

from the illicit market.¹ Studies have repeatedly shown that needle exchange programs do not encourage increased drug use, and many even show decreases in injection frequency.² A mathematical model constructed by researchers in New Haven, CT, estimates that new HIV incidence can be reduced by an estimated 33% in needle exchange program clients.³ A CDC-sponsored research team later suggested that this may be an underestimate.²

While the ENCORE program has reached only a fraction of the estimated 10,000 injecting drug users in Rhode Island, its effect has been significant. From April 1995 through December 1999, over 1,500 individuals were enrolled into the ENCORE program. 78% of the clients were residents of Providence County, from where 82% of the state's AIDS cases were reported. At enrollment, 99% of ENCORE clients indicated that they had reused syringes while injecting drugs and

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48% had shared syringes with another person. 21% of clients had shared syringes more than 10 times in the month prior to enrollment in ENCORE. The risk of disease transmission is extremely high in this population, as clients inject drugs an average of 71 times in the 30 days before enrollment.

In 1998, a follow-up analysis was undertaken with ENCORE clients to

evaluate the effectiveness of the program and its impact on the risk-taking behaviors. The follow-up involved 123 clients who had remained in the program for at least one month and completed a post-enrollment questionnaire. The demographic and risk factors at enrollment were highly representative of the general ENCORE population at enrollment.

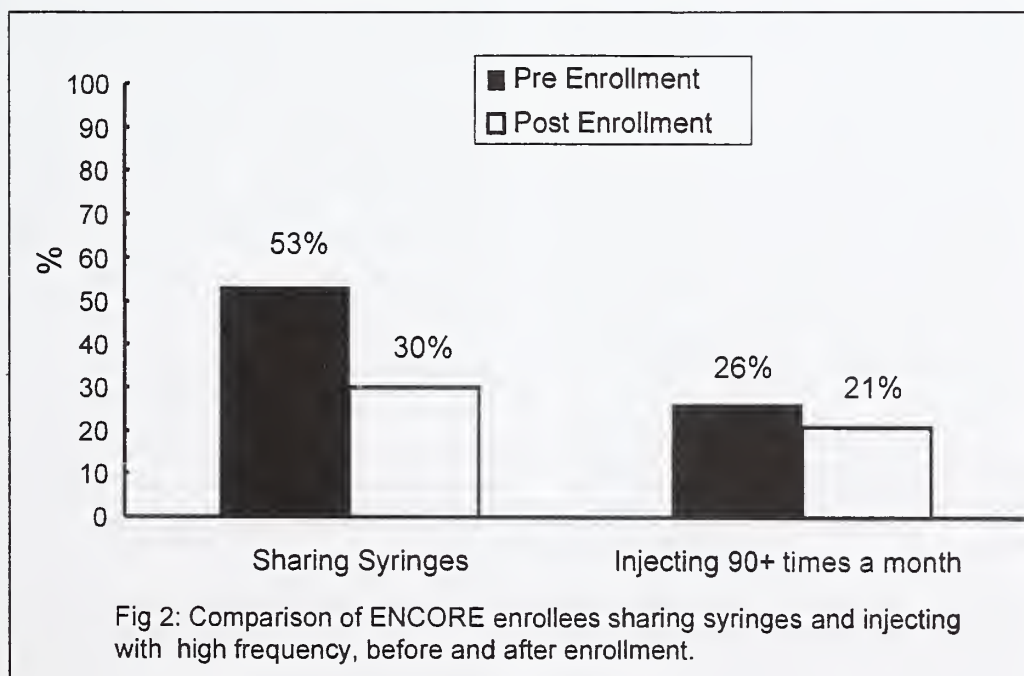
The follow-up analysis showed that the number of ENCORE clients reusing needles 30+ times decreased by 50% after enrolling in ENCORE. The frequency of syringe sharing overall fell from 53% of clients to 30%. (Figure 2) Clients with the highest frequency of injections (90+ times a month) and therefore those at highest risk, decreased their injection frequency by 19% after enrollment in ENCORE.

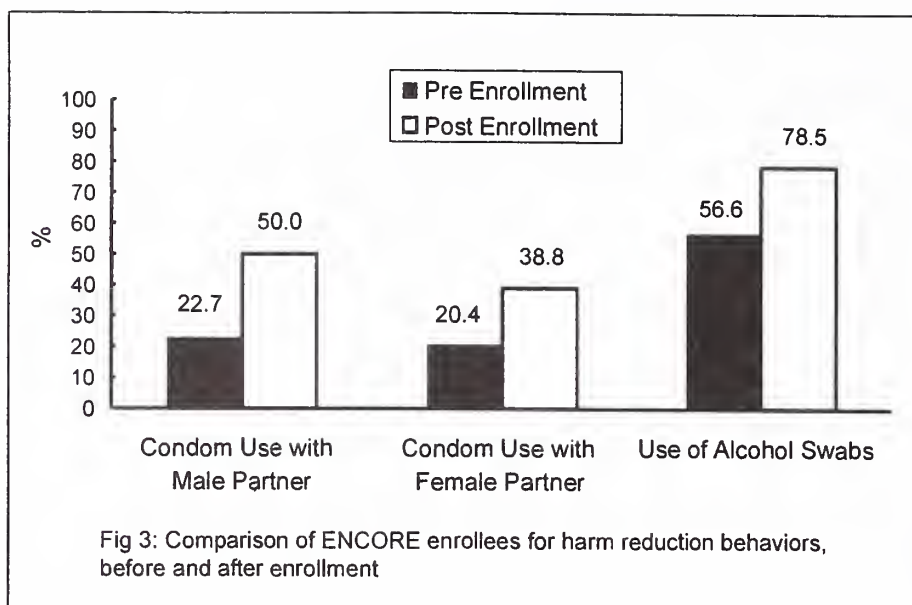
The reduction of at-risk behaviors in ENCORE clients was not limited to injecting drug use behavior only. Enrollees completing the follow-up were more likely to use condoms with their sexual partners, to utilize alcohol swabs to clean the injection site, and to enroll in drug rehabilitation or counseling programs. (Figure 3) It must be noted, however, that this follow-up analysis was cross-sectional, and therefore these findings cannot be projected as sustained behaviors beyond the time of the follow-up survey.

Over five years, the ENCORE program has implemented a harm-reduction model in a population at high risk for HIV, hepatitis B and C and other bloodborne infections. Staffed almost entirely by volunteers, the ENCORE program has reached a population once thought unreachable. With the implementation of new legislation curbing the penalties for syringe possession and the continued expansion of the ENCORE program, it is hoped that fewer residents of Rhode Island will be contracting HIV and other diseases from infected syringes.

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Blood-borne Pathogens, the Physician and the Board of Medical Licensure and Discipline

Milton W. Hamolsky, MD

In 1991 a cluster of six patients were reported who had acquired HIV infection within the practice of a Florida dentist who was himself HIV-infected. Poignant testimony by one of these patients, a young woman, before Congress led to a flurry of media coverage, various state legislative actions, actions by the courts and a growing national anxiety about the possibility that health care workers (HCWs) could inadvertently spread the threatening AIDS virus.

Following this incident, the Center for Disease Control and Prevention (CDC) published its plan to list those exposure-prone invasive procedures which should not be performed by health care workers infected with HIV unless there had been review by an "expert panel." The intent of this proposal was to provide for a case by case determination of whether an HIV-infected HCW could perform an invasive procedure. In addition, CDC emphasized the need for all HCWs to adhere to universal precautions, treating blood and other body fluids as if they contained bloodborne infectious agents, emphasizing hand washing, protective barriers (rubber gloves, goggles etc) and special care in the use and disposal of needles or other

sharp instruments. Such proposals implied that health care workers should know their HIV or hepatitis B serology and raised the controversial issue of what constituted "exposure-prone" procedures.

Subsequently in 1992 the American Medical Association (AMA) stated that "a physician who knows that he or she is HIV seropositive should not engage in any activity that creates an unidentified risk of transmission of the disease to others. A physician who has HIV infection should consult colleagues as to which activities the physician can pursue without creating a risk to patients." This opinion also posed the serious problem of "informed consent." Should a physician know whether he or she is seropositive and, if so, is it his or her duty to inform any patient of this fact before engaging in any procedure which might risk transmission?

At the time in the emotionally charged atmosphere surrounding HIV/AIDS, these recommendations elicited considerable controversy. It was noted that data showing provider-to-patient transmission of HIV were lacking. Indeed, subsequent studies have noted that

Abbreviations Used:

AIDS	acquired immune deficiency syndrome
AMA	American Medical Association
CDC	Centers for Disease Control and Prevention
HCW	health care worker
HIV	human immunodeficiency virus

the case of the Florida dentist was essentially the only documented case of transmission of AIDS from a health care worker to patients. One additional possible incident of health care worker-to-patient transmission has been reported but not confirmed. These findings have led to the current consensus - that the risk for transmission from a health care worker to a patient is so extremely small that it negates the recommendation that said health care worker should not engage in particular procedures with patients. In actuality the experience to date revealed a greater risk of transmission from a patient to the physician than the reverse.

The fundamental issues have been somewhat obscured by late twentieth century phenomena. The American pen-

chant for polls led to a flurry of these in which the public indicated a preference that HCWs should know whether they were HIV-infected and if so, divulge this to their patients. A court action ruled that a hospital had the right to expel a resident from his training program because of the discovery of a positive HIV test (the resident maintained that he had contracted his disease from a patient in the hospital). Anecdotes abounded of discrimination against HCWs, as well as against patients who were discovered to be HIV-infected (or even simply suspected thereof). The lack of sufficient data to warrant specific guidelines began to dominate the discussions.

Specific analyses were undertaken to address the question of HCW-to-patient transmission of HIV. From 1981 through 1994, 14,591 cases of AIDS among HCWs in the United States were reported to the CDC. They accounted for 4.8% of the 304,651 total reported AIDS cases. HIV infection in the absence of AIDS is not a reportable condition in many states. One Health Department reported that a patient is more likely to die from general anesthesia or from an adverse reaction to penicillin than from treatment by an HIV-positive health professional. It was reported that the Congress, over the scientific objection of CDC officials, recommended that HIV-positive healthcare workers who perform exposure-prone procedures notify prospective patients of their seropositivity. Congress also directed all states to adopt guidelines "equivalent to those of CDC," but the CDC publicly announced that it would allow the states leeway to deviate from such provisions.

Following extensive expert consultations, the Rhode Island Department of Health reported its policy guidelines in July of 1992. These include the following:

- Institutions are charged with monitoring and assuring compliance of their members, non-members and employees with universal precautions.
- The health facility licensing programs will incorporate review of infection control and universal precautions into their annual and other reviews.

One Health Department reported that a patient is more likely to die from general anesthesia or from an adverse reaction to penicillin than from treatment by an HIV-positive health professional.



- Complaints regarding an individual practitioner's failure to follow universal precautions will be investigated by the Board of Medical Licensure and Discipline or other appropriate licensing board.
- Mandatory continuing education requirements of two hours every three years on universal precautions, infection control, and OSHA regulations.
- The Rhode Island Department of Health will not list specific hazardous procedures but will judge each case on an individual basis.
- The Department will not require health care workers to undergo HIV or hepatitis B testing. It is recommended that those who are at risk because of occupational exposure be tested voluntarily.
- The Department recommends that infected workers seek advice from a state-appointed and authorized review panel. This review panel has not yet been activated, and the Department has not received any requests for actions. An ad hoc committee on HIV-infected healthcare workers was charged by the Department to develop recommendations based on science and sensitivity to the best interest of society and the committee has enthusiastically accepted this responsibility.

Based on the accumulating evidence and changes in attitudes towards HIV, the CDC and the AMA have modified their initial guidelines to be more general. Pragmatically speaking, hepatitis B and hepatitis C are recognized as posing much greater problems than HIV, in terms of seroprevalence and HCW-related transmission.

However, as far as the Board of Medical Licensure and Discipline is concerned, the basic fundamental issues remain - to balance protection of the public on the one hand with the proper investigation and due process of confidentiality and individual privacy of the involved physician on the other hand. The Board has initiated discussions on the interrelated issues of HCW serologic testing, disclosure and specific exposure prone procedures but has not yet defined specific guidelines. As is its usual practice, the Board would consider such questions on an individual basis. The Board welcomes suggestions or recommendations from any interested party.

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CME/CE Background Information

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This enduring material is designed for physicians licensed in Rhode Island.

CME/CE OBJECTIVES

After completing this CME activity, the reader will be able to meet the following objectives.

1. The reader will identify the options for prevention, including vaccine, of Hepatitis B.
2. The reader will identify the opportunities for exposure to and the options for treatment of hepatitis C.
3. The reader will identify the risks of non-occupational HIV exposure and the options for postexposure HIV prophylaxis in cases of non-occupational exposures.
4. The reader will identify the risks of occupational HIV exposure, and the treatment options.
5. The reader will identify the optimum techniques for discussing possible blood-borne pathogen exposure with health care workers, including site of discussion, follow-up timetable, and medical concerns.
6. The reader will identify some of the legal issues regarding testing for blood-borne pathogens.
7. The reader will identify what the ENCORE program in Rhode Island has accomplished.
8. The reader will identify state and federal regulations vis a vis infected health care workers.

NEEDS ASSESSMENT

The State of Rhode Island requires continuing medical education credits in blood-borne pathogens for licensure.

ACCREDITATION STATEMENT

Brown University School of Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. This activity has been planned and implemented in accordance with the Essential Areas and Policies at the ACCME.

CREDIT DESIGNATION

Brown University School of Medicine designates this education activity for 2 hours in category 1 credit toward the AMA Physician's Recognition Award. Credit can be obtained by reading the issue and completing the quiz on the following page. The estimated time for completion of this activity is 2 hours.

DATE OF ORIGINAL RELEASE

This issue was published in July 2000. This activity is eligible for CME credit through May 2001.

FACULTY DISCLOSURE

In accordance with the disclosure policy of Brown University School of Medicine as well as standards set forth by the Accreditation Council on Continuing Education (ACCME), speakers have been asked to disclose (1) any significant financial or any other relationship with the manufacturers(s) or any commercial products(s) and/or provider(s) of commercial services discussed in any educational presentation and (2) with any commercial supporters of this activity.

The intent of this policy is not to prevent an author with a potential conflict of interest from making a presentation. It is merely intended that any potential conflict should be identified openly so that the reader may form his/her own opinion.

Stephen L. Boswell, MD; Consultant: Glaxo Wellcome, Agouron, Chiron; Speaker's Bureau: Merck, Agouron; Research Support: Abbott, Marck, Chiron, Agouron; Kenneth A Mayer, MD; Research Support: Triangle; Gilead; Immune Response Corp., Roche; Speaker's Bureau: Abbott, Glaxo Wellcome, Bristol Myers Squibb, Dupont, Roxane; Maria Mileno, MD; Speaker's Bureau: Merck

The following authors have disclosed that they have no commercial relationships to report: E. Timothy Latta, Jane-ellen Cassidy, RN, Brent Canning, Molly Stenzel, MD, Jeffrey Kwong, Anne Spaulding, MD, Roberta Singal, Marguerite A. Neill, MD, Michael Tauber, Albert Osei, MD, Scott Allen, MD, Milton Hamolsky, MD, Rebecca Ballard, MD

ACKNOWLEDGEMENT

The material contained in this issue is a result of the editorial work by Marguerite Neill, MD, guest editor. The opinions expressed herein are those of the authors and do not necessarily reflect the views of the sponsors, publisher or the planning committee.

TO OBTAIN CREDIT

To obtain credit, please submit answer grid and \$25 fee to Office of Continuing Medical Education, Brown University. Respondents must receive a score of 70 or higher for credit.

CE CREDIT FOR NURSES

This activity has been approved for 2.4 contact hours by the Rhode Island State Nurses Association, which is accredited as an approver of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation.

To obtain credit, please submit answer grid and \$25 fee to Rhode Island Medical Society, 106 Francis Street, Providence, RI 02903. Respondents must receive a score of 70 or higher for credit.

CME/CE Blood-Borne Pathogen Questions

1. What steps must be taken following a high risk occupational HIV exposure?
 - A) Furlough the exposed worker from patient care duties
 - B) Offer a postexposure prophylaxis regimen expeditiously
 - C) Test the exposed person for hepatitis B and C as well as HIV at exposure, and at 6 weeks, 3 and 6 months later
 - D) Reassure the exposed person that the risk of transmission of HIV is low
 - E) B, C and D only
2. All of the following statements regarding occupational exposure to HIV are true except:
 - A) It is rare for workers in RI to encounter HIV infected persons.
 - B) The overall risk of HIV infection after a percutaneous exposure is approximately 0.3% yet this risk varies depending upon the depth of the injury and the extent of blood contamination
 - C) Non-bloody body fluids of HIV infected individuals carry little to no risk of transmission of HIV to health care workers.
 - D) Events most likely to lead to an exposure include unsafe sharps disposal, recapping of needles and unexpected patient movements during procedures.
3. The current treatment recommendation for post-exposure prophylaxis for hepatitis C is:
 - A) Immune globulin.
 - B) Interferon injections.
 - C) Hepatitis C vaccine.
 - D) No prophylaxis is recommended.
4. Acute infection with hepatitis C following a percutaneous exposure will:
 - A) Usually present with jaundice.
 - B) Manifest seroconversion within a week of exposure.
 - C) Most reliably be initially detected by transaminase elevation.
 - D) Require restriction of health care worker activities that involve direct patient care.
5. Which statement concerning percutaneous injury with a needle contaminated with hepatitis C virus is false?
 - A) The risk of acquiring hepatitis C is between that for HIV and hepatitis B.
 - B) The average incidence of HCV seroconversion after needlestick injury is 1.8%.
 - C) Once established, all hepatitis C infections eventually progress to cirrhosis.
 - D) The incubation period for HCV is about 6 weeks.
6. Which of the following best describes current recommendations regarding hepatitis B vaccination of health care workers:
 - A) Booster doses of hepatitis B vaccine every 5 years following completion of initial three-dose vaccine series.
 - B) Serologic testing following completion of vaccine series to confirm the presence of protective antibody titer.
 - C) Periodic serologic testing to demonstrate persistence of adequate levels of protective antibody.
 - D) All of the above.
7. The presence of which of the following in the blood is associated with a markedly increased risk of transmission of HBV?
 - A) Hepatitis B surface antigen (HBsAg)
 - B) Antibody to hepatitis B core antigen (HBcAb)
 - C) Hepatitis B antigen (HBeAg)
 - D) Antibody to hepatitis B surface antigen (HBsAb)
8. Nonoccupational post-exposure prophylaxis for HIV could be recommended in all but which one of the following circumstances:
 - A) Sexual assault
 - B) Needlestick from a discarded syringe on a playground
 - C) Woman with a sporadic sexual encounter 12 hours earlier with a bisexual man
 - D) Sex worker who refuses referral for counseling
9. Which of the following statements on the use of post-exposure prophylaxis (PEP) to prevent HIV transmission in non-occupational settings is false?
 - A) PEP has prevented HIV transmission in animal models.
 - B) A retrospective case-control study indicated that health care workers who took AZT after occupational exposures were 1/5th as likely to become HIV-infected as those who did not take AZT.
 - C) PEP has been proven to be effective in a prospective, randomized clinical trial.
 - D) Perinatal HIV transmission is decreased when mothers use antiretroviral therapy.
10. Which of the following statements regarding post-exposure evaluation is correct?
 - A) The evaluation can be done most efficiently by HCWs themselves by looking at a protocol on the Internet.
 - B) No specific training is necessary for those conducting post-exposure evaluations.
 - C) Blood and body fluid exposures are invariably viewed as annoyances by HCWs.
 - D) The continued availability of the exposure evaluator to the HCW is an important component to the management of blood and body fluid exposures.
11. The police bring to your office a person arrested for sexual assault. The victim has asked the police whether the suspect is HIV+. The suspect refuses to consent to a blood test. What can you legally do?
 - A) Test the patient, without his consent
 - B) Ask the police to obtain a court order for the blood test.
 - C) You can never test the patient without his consent.
 - D) Ask for the opinion of an "exposure evaluation group" before testing the patient's blood.
12. Which of the following statements on needle exchange programs is false?
 - A) In general, the evidence for needle exchange programs has been positive: no increased drug use, but lower re-use of needles and lower rates of HIV incidence for intravenous drug users.
 - B) ENCORE, the state of Rhode Island's needle exchange program, requires an enrollee to exchange an old syringe for a new syringe.
 - C) A follow-up evaluation of ENCORE showed that it reduced the re-use of needles, but had no significant impact on risk-taking behaviors.
 - D) Needle-exchange programs have traditionally drawn support from the medical and public health communities.
13. Which statement is true?
 - A) Federal law requires a physician who knows that s/he is infected with hepatitis B to inform any patient of this fact before engaging in any procedure which might risk transmission.
 - B) The Rhode Island Department of Health requires health care workers to undergo Hepatitis B testing.
 - C) Patients are at greater risk of HIV transmission from health care workers, than health care workers are from patients.
 - D) No statement is true.

BLOOD-BORNE PATHOGENS

CME/CE Registration Form

Print or type

Circle one response for each question.

- | | | | | | |
|-----|---|---|---|---|---|
| 1. | A | B | C | D | E |
| 2. | A | B | C | D | |
| 3. | A | B | C | D | |
| 4. | A | B | C | D | |
| 5. | A | B | C | D | |
| 6. | A | B | C | D | |
| 7. | A | B | C | D | |
| 8. | A | B | C | D | |
| 9. | A | B | C | D | |
| 10. | A | B | C | D | |
| 11. | A | B | C | D | |
| 12. | A | B | C | D | |
| 13. | A | B | C | D | |

Name _____

Address _____

City, State, Zip _____

Phone () _____

Fax () _____

e-mail _____

____ Hospital ____ Private Practice ____ Resident ____ Intern

____ Other _____

DEADLINE FOR SUBMISSION: PHYSICIANS

For credit to be received, please mail your registration with \$25 fee to Office of Continuing Medical Education, Brown University School of Medicine, Box G-A2, Providence, RI 02912. Submit your answers no later than May 31, 2001.

KEEP A COPY FOR YOUR FILES.

Retain a copy of your answers and compare them with the correct answers, which will be made available upon request, and receipt of submission requirements.

DEADLINE FOR SUBMISSION: NURSES

For credit to be received, please mail your registration with \$25 fee to Rhode Island Medical Society, 106 Francis Street, Providence, RI 02903. Please submit your answers no later than May 31, 2001.

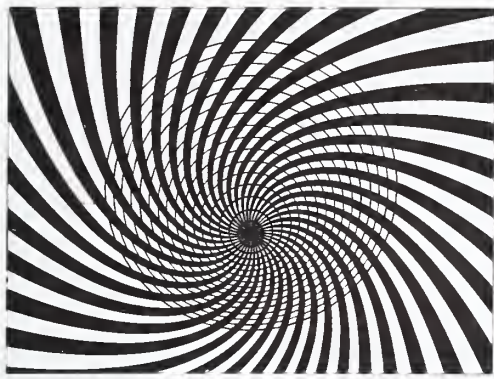
EVALUATION

Please evaluate the effectiveness of the CME/CE activity on a scale of 1 to 5 (1 being poor; 5 being excellent) by circling your choice.

- | | | | | | |
|--|---|---|---|---|---|
| 1. Overall quality of this CME/CE activity | 1 | 2 | 3 | 4 | 5 |
| 2. Content | 1 | 2 | 3 | 4 | 5 |
| 3. Format | 1 | 2 | 3 | 4 | 5 |
| 4. Faculty | 1 | 2 | 3 | 4 | 5 |
| 5. Achievement of educational objectives | | | | | |
| * The reader will identify the options for prevention, including vaccine, of Hepatitis B. | 1 | 2 | 3 | 4 | 5 |
| * The reader will identify the opportunities for exposure to and the options for treatment of hepatitis C. | 1 | 2 | 3 | 4 | 5 |
| * The reader will identify the risks of non-occupational HIV exposure and the options for postexposure HIV prophylaxis in cases of non-occupational exposures. | 1 | 2 | 3 | 4 | 5 |
| * The reader will identify the risks of occupational HIV exposure, and the treatment options. | 1 | 2 | 3 | 4 | 5 |
| * The reader will identify the optimum techniques for discussing possible blood-borne pathogen exposure with health care workers, including site of discussion, follow-up timetable, and medical concerns. | 1 | 2 | 3 | 4 | 5 |
| * The reader will identify some of the legal issues regarding testing for blood-borne pathogens. | 1 | 2 | 3 | 4 | 5 |
| * The reader will identify the accomplishments of the state ENCORE program. | 1 | 2 | 3 | 4 | 5 |
| * The reader will identify federal and state regulations vis a vis infected health care workers. | 1 | 2 | 3 | 4 | 5 |
| 6. This CME/CE activity provided a balanced, scientifically rigorous presentation of therapeutic options related to the topic, without commercial bias. | 1 | 2 | 3 | 4 | 5 |

Please comment on the impact that this activity might have on your practice of medicine.

Additional comments and/or suggested topics for future CME or CE activities.



IMAGES IN MEDICINE

Neurocysticercosis

Paolo D. Olcese, MD, and William W. Mayo-Smith, MD

A 29 year-old female with a history of recent travel to Guatemala presented to the Emergency Department with new onset seizures. The patient was referred for an MRI of the brain at the time of admission. Figure 1 is a T1 weighted image which demonstrates the typical imaging findings of a cysticercus in the colloidal stage. The lesion is isointense to cerebrospinal fluid and there is a small mural nodule representing the scolex or dead parasite (arrow). Figure 2 is a FLAIR sequence which reveals bright edema caused by host reaction to the dying parasite. Figure 3 is a Gadolinium enhanced T1 weighted image demonstrating peripheral enhancement (arrow) indicative of larval degeneration and host inflammatory reaction. Figure 4 is a CT image in a different patient demonstrating calcification of a burned out infection with peripheral granulomata (arrow).

Neurocysticercosis is a parasitic infection caused by the tapeworm *Taenia Solium*. It is the most common infection of the central nervous system worldwide and patients typically present with seizures. Neurocysticercosis has four stages of activity in the central nervous system, each having a characteristic imaging finding on CT and MR. The vesicular stage is seen with a viable parasite and on imaging one sees a small cyst with no enhancement. The

Abbreviations Used:

CT	computed tomography
FLAIR	fluid attenuation inversion recovery sequence
MRI	magnetic resonance imaging

colloidal stage occurs after the parasite has died and the host immune system reacts against the degenerating cysticerci. In this stage there is enlargement of the cyst, thickening of the capsule, edema and peripheral enhancement as in this patient. The third or granular nodular stage is marked by retraction of the larva with secondary mineralization. In the fourth or nodular calcified stage (Figure 4) the lesions are small and hyperdense on CT and may be overlooked on MRI.

REFERENCES

- Palacios E, Salgado Lujambio P, Rojas Jasso R. Computed tomography and magnetic resonance imaging of neurocysticercosis. *Seminars in Roentgenology* 1997; 32:324-34.

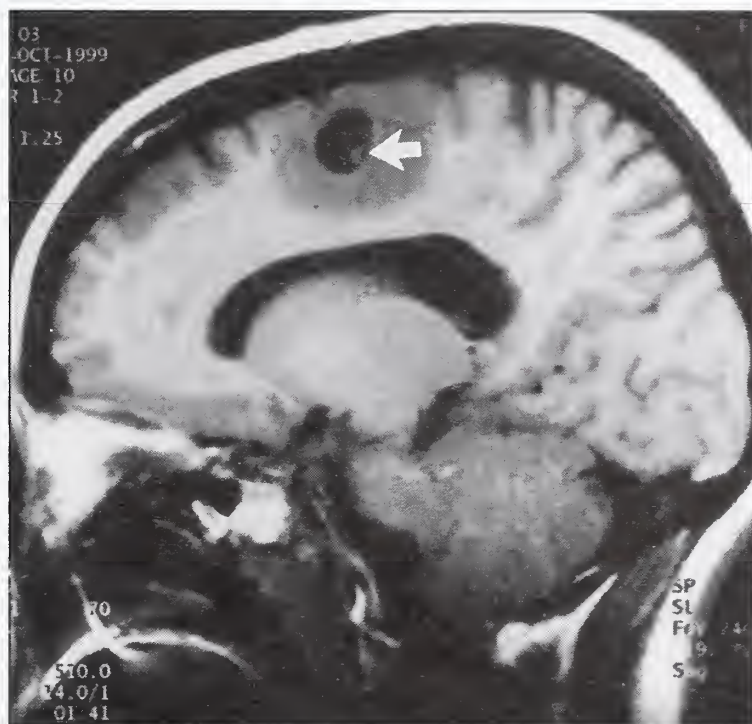


Figure 1.

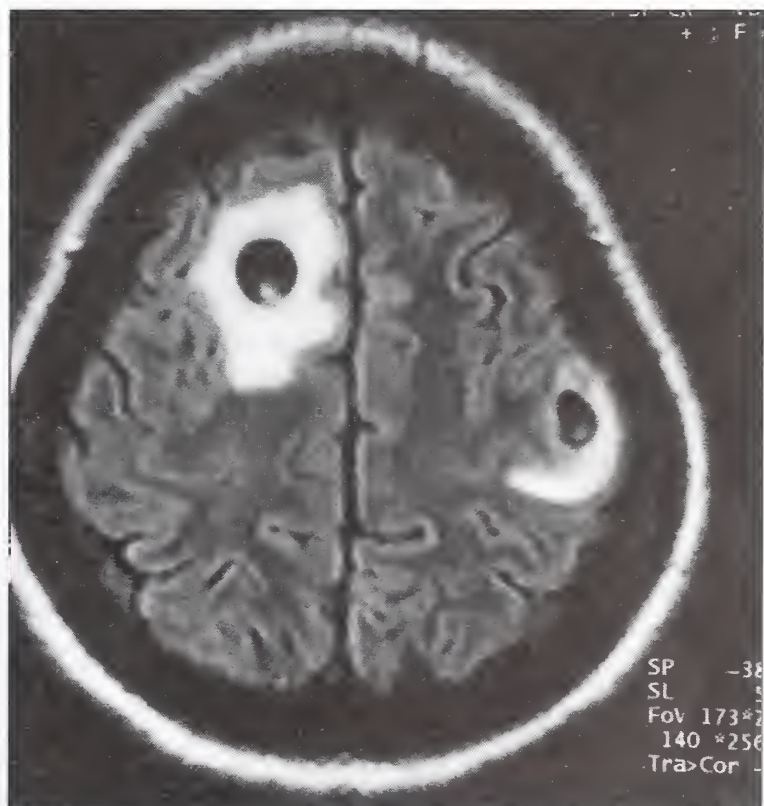


Figure 2.

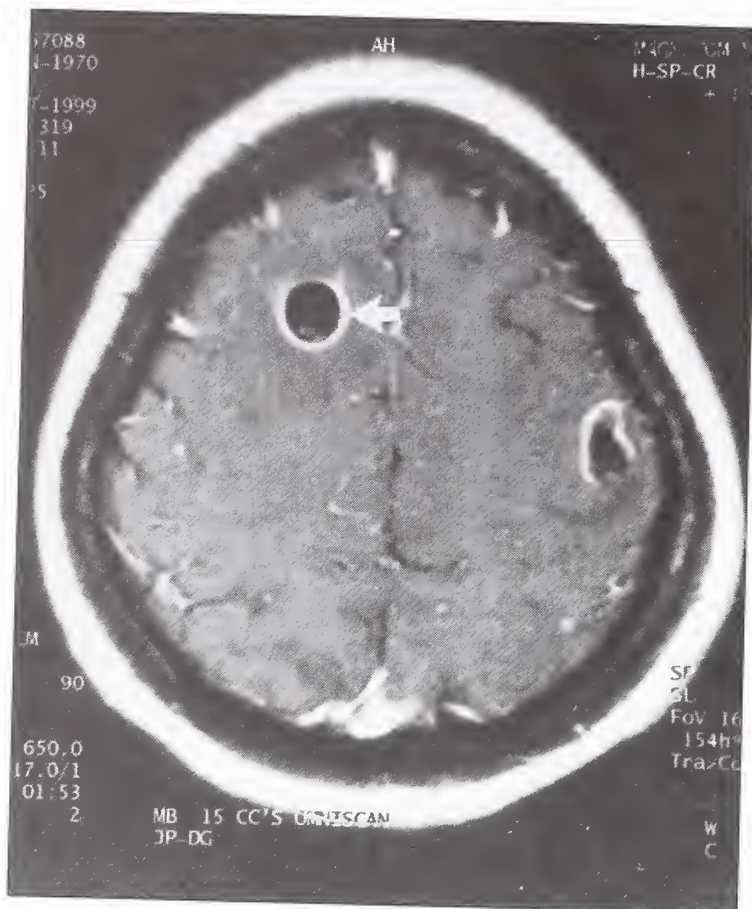


Figure 3.

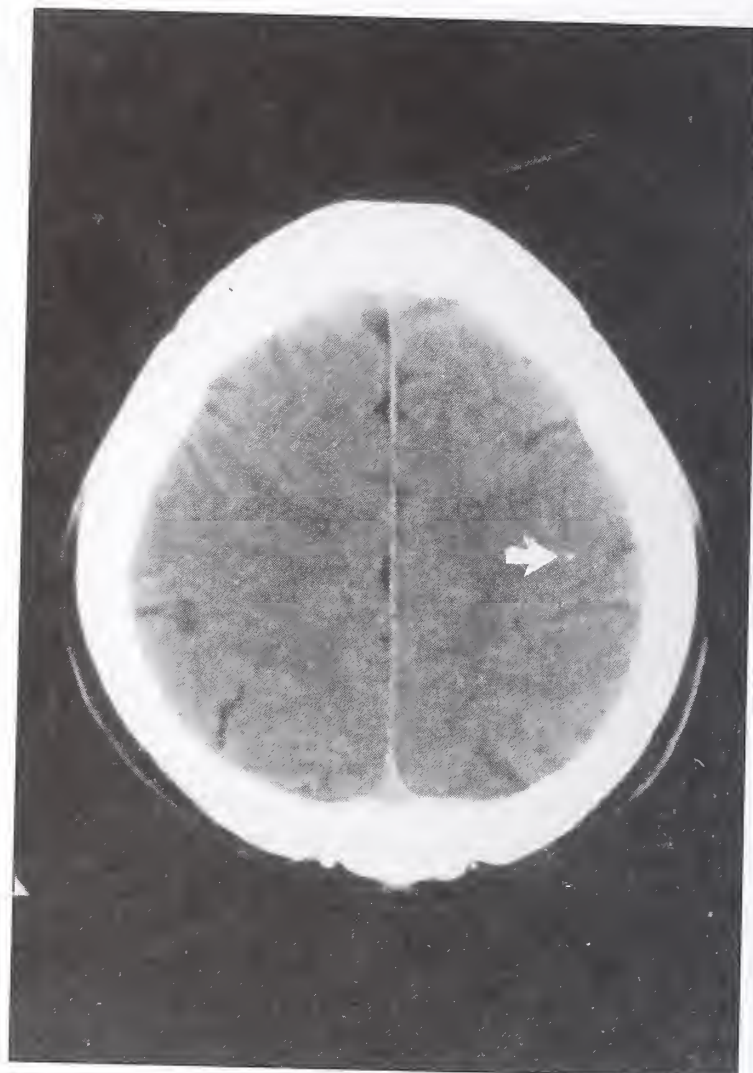


Figure 4

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 phone: (401) 444-5184
 fax: (401) 444-5017





How Does Rhode Island Rank Nationally on Quality Indicators?

David R. Gifford MD, MPH, and Raymond Maxim MD

In 1999, the Health Care Financing Administration (HCFA) asked each Peer Review Organization (PRO) in the country to focus on eight specific clinical areas: acute myocardial infarction (AMI), heart failure (HF), stroke, atrial fibrillation (A-fib), pneumonia, diabetes, mammography utilization and influenza/pneumococcal vaccinations. Based upon published national guidelines, HCFA developed a national set of quality indicators for each of these areas. The quality indicators principally focus on treatments and interventions that can improve patient outcomes and survival such as prescribing aspirin, beta-blockers, ACE-inhibitors and thrombolytics for patients with an AMI; ACE-inhibitors for patients with heart failure; anticoagulation for patients with atrial fibrillation or stroke; and prescribing antibiotics in a timely fashion for patients hospitalized with pneumonia (Table 1).

To collect information on these indicators, HCFA used ICD-9 codes for AMI, HF, A-fib, stroke, and pneumonia to identify all Medicare beneficiaries discharged from hospitals in Rhode Island during a six-month period (July 1998 through Dec 1998). After selecting a random sample of 750 patients (or all patients if fewer than 750 were identified), the medical records were sent to one of two clinical data abstraction centers (CDAC). Nurses, following previously validated protocols, abstracted information from the medical record. The inter-rater and intra-rater reliabilities for these abstraction centers are continuously tested and are of acceptable levels. The diagnosis is confirmed through information in the medical record. For example, patients with a principal ICD-9 diagnosis of AMI must have evidence of an AMI in the medical record including enzyme (i.e. LDH, CK-MB or troponin) consistent with AMI or symptoms along with EKG findings consistent with AMI. Information on contraindications to each medication or therapy is also abstracted. The final quality indicators are calculated excluding patients who die, are transferred, or who leave against medical advice. In addition, the quality indicators exclude all patients with contraindications for the treatment or therapy being evaluated. For example, patients with history or risk of bleeding are excluded from

Abbreviations Used:

A-fib	atrial fibrillation
AMI	acute myocardial infarction
CDAC	clinical data abstraction centers
EKG	electrocardiogram
HCFA	Health Care Financing Administration
HF	heart failure
LDH	lactate dehydrogenase
MCO	managed care organization
PRO	Peer Review Organization

the use of aspirin following an AMI and warfarin for A-fib quality indicators.

Results from the initial data collection effort are shown in Table 1. When compared to the nation, Rhode Island ranks near the top in the use of beta-blockers in AMI, ACE inhibitors for HF, appropriate use of antibiotics for patients with pneumonia, and warfarin for patients with atrial fibrillation. However, there is still room for improvement within some of these areas. For example, more than a third of patients with atrial fibrillation who do not have contraindications to using warfarin, did not receive warfarin.

For other quality indicators, we rank much lower and have more opportunity to improve. For early use of aspirin, smoking cessation counseling, initiation of antibiotics under 8 hours for patients with pneumonia, and use of influenza and pneumococcal vaccines, we rank in the lower half nationally. For example, more than three-quarters of patients in Rhode Island who smoke and experienced an AMI did not have any documentation in the medical record about smoking cessation counseling by discharge. The data are slightly, but not much better for patients with HF who smoke (31.5% have documentation of smoking cessation counseling). However, smoking status is documented in over 90% of patients admitted with HF. One of the strongest predictors of patients stopping smoking is their physician's recommendation to stop smoking.

In order to improve in these areas, approaches both at

the local hospital level and at the state level need to be initiated. Currently, Rhode Island Quality Partners (RIQP) is working with all the acute care hospitals, physician groups and Medicare managed care organizations (MCOs) to develop strategies to improve performance in areas such as time to antibiotics, immunizations and smoking cessation counseling. All the acute care hospitals, MCOs, physicians, American Heart Association, Department of Health, and others meet monthly to discuss approaches to increase performance in all hospitals for each of these quality indicators. Physician involvement in these efforts is vital to the development of successful interventions. Any physicians who are interested in participating in these efforts, should contact David Gifford at RIQP at (401) 528-3200.

David R. Gifford, MD, MPH, is Clinical Coordinator, RIQP; and Assistant Professor of Medicine and Community Health, Brown University.

Raymond Maxim, MD, is Clinical Coordinator, RIQP and internist at Roger William Medical Center.

CORRESPONDENCE:

David R. Gifford, MD, MPH
Phone: (401) 528-3261
fax: (401) 528-3210

Table 1. National HCFA quality indicators with RI rates and national ranking.

Condition	Quality Indicator focus	RI Rate	National Rank
Myocardial Infarction	Aspirin use at admission	81.7	37
	Aspirin use at discharge	86.9	17
	Beta-Blocker use at admission	75.7	5
	Beta-Blocker use at discharge	79.2	11
	ACE-inhibitor use for systolic dysfunction	83.3	3
	Thrombolytic or PTCA use	48.0	--
	Smoking cessation counseling by discharge	25.9	48
Heart Failure	ACE-inhibitor use at discharge for LVSD	87.0	2
	Discharge education about disease management*	3.0	--
Atrial Fibrillation	Warfarin use	59.4	12
Stroke/Transient Ischemic Attacks	Antiplatelet use	82.5	--
	Avoid sublingual nifedipine	95.3	--
Pneumonia	Antibiotic administration within 8 hours	79.5	44
	Appropriate antibiotics initiated**	83.2	7
	Blood cultures prior to antibiotics	81.0	36
	Influenza vaccination before discharge	9.6	46
	Pneumococcal vaccine before discharge	6.8	44

For detailed definitions and specifications for any of the quality indicators, including the inclusion and exclusion criteria used to calculate the quality indicator, please contact Madeleine Deschenes at RIQP at 528-3200.

-- = Data not yet available

* Discharge education for CHF should include all of the following elements (rates for each individual element are also shown): medications (81%), weight monitoring (7%), diet (74%), activity level (65%), follow-up appointment (88%), what to do if symptoms worsen (20%).

** Appropriate antibiotic initiated per American Thoracic Society and American Infectious Disease Society guidelines

Non-ICU admissions:

- β-lactam monotherapy IV, *or*
- β-lactam (IV) + macrolide (IV or PO), *or*
- Quinolone monotherapy (IV or PO).

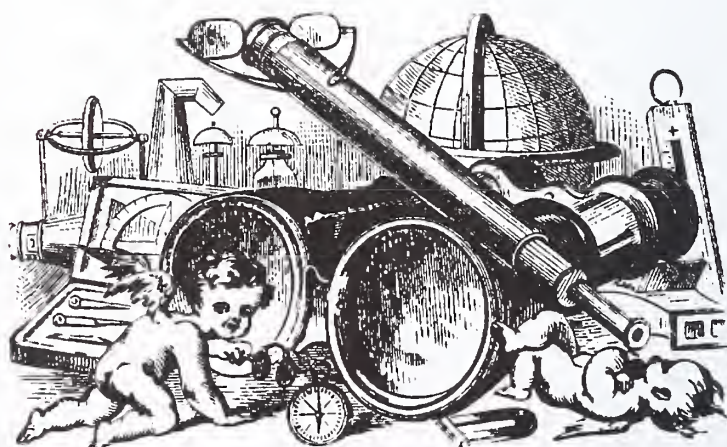
ICU admissions:

- β-lactam (IV) + macrolide (IV), *or* -β-lactam (IV) + -quinolone (IV)

If documented β-lactam allergy:

The analyses upon which this publication is based were performed under Contract Number 500-96-P519, entitled "Utilization and Quality Control Peer Review Organization for the State of Rhode Island," sponsored by the Health Care Financing Administration, Department of Health and Human Services. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.





Vital Statistics

Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report

Provisional Occurrence Data
from the
Division of Vital Records

Underlying Cause of Death	Reporting Period			
	July 1999	12 Months Ending with July 1999		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	266	3,060	309.6	3,772.5
Malignant Neoplasms	241	2,478	250.7	7,016.5
Cerebrovascular Diseases	39	551	55.7	653.5
Injuries (Accident/Suicide/Homicide)	29	359	36.3	6,250.5
COPD	42	503	50.9	427.5

Vital Events	Reporting Period		
	January 2000	12 Months Ending with January 2000	
	Number	Number	Rates
Live Births	759	12,763	12.9*
Deaths	1,116	9,980	10.1*
Infant Deaths	(10)	(91)	7.1#
Neonatal deaths	(7)	(74)	5.8#
Marriages	276	7,772	7.9*
Divorces	180	2,710	2.7*
Induced Terminations	390	4,785	374.9#
Spontaneous Fetal Deaths	11	863	67.6#
Under 20 weeks gestation	(7)	(797)	62.4#
20+ weeks gestation	(4)	(66)	5.2#

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

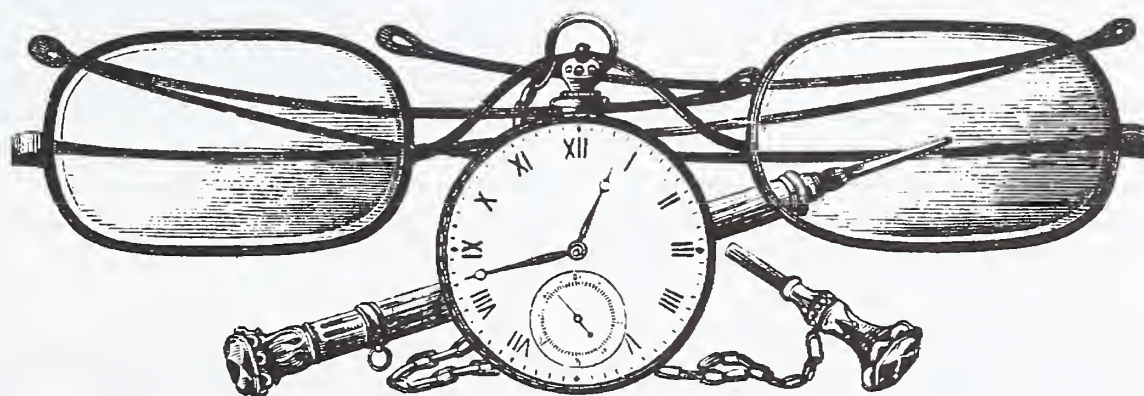
(b) Rates per 100,000 estimated population of 988,480

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population

Rates per 1,000 live births



FORTHCOMING

August *Medicine & Health/Rhode Island*

Medical Education with a special insert:
Instructions for Physician Reporting of
Communicable, Environmental and
Occupational Diseases

NINETY YEARS AGO

✿ [JULY, 1910] ✿

An Editorial discussed the proposed Medical Library. "In courteous but none the less compelling terms," the Providence Public Library had given the Medical Society two years to move their 30,000 volumes, which took up nearly 1/5 the contents of the entire Providence Public Library building. A Medical Society planning committee took Philadelphia's College of Physicians library as their model. That new building, built at a cost of \$400,000, had stacks for 300,000 volumes. Medical society libraries grew as members bequeathed personal libraries: "...so high is the sense of professional duty in Philadelphia that it has become so common a custom for the Fellows to bequeath their libraries to the College that . . . anyone who neglected to follow this salutary rule imperils his future." The committee expected the Rhode Island Medical Society collection to expand: "What Philadelphia has done may be done in Providence, " if at "longo intervallo." [The need for library space, coupled with the Medical Society's desire to consolidate its medical education activities and services to members, propelled the Society to locate at 106 Francis Street.]

Frank R. Fulton, MD, in "Some observations of meningitis with especial reference to the danger of administration of the serum," reported on Rhode Island's waning meningitis epidemic. (In 1908 he treated 25 patients with the Flexner antiserum; in 1909, 9 cases.) He calculated a 20% mortality rate, but upped it to 30% when he included those patients who were moribund and chronic. For many patients, the treatment prompted "rapid convalescence, almost complete freedom from complications or sequelae." He conceded the dangers of lumbar punctures, and recommended precautions (e.g., children should receive 15 cc of serum, not 30cc.).

W.L. Chapman, MD, pathologist at St Joseph's Hospital, urged physicians to speak as experts to legislative committees, such as those investigating stream pollution, the ventilation of shops and stores, and juvenile delinquency. To understand delinquency, physicians must look beyond physical attributes. "Never mind about the character as revealed by the facial angle or the malocclusion of the teeth, forget the significance of the bizygomatic breadth, the cranio-mandibular index . . . but remember that bad homes mean tuberculosis, chronic indigestion, adenoids and idleness, and that bad books and pictures and a few teachers experienced in crime transform the beautiful and innocent child into the tough and criminal." With his final salvos, he condemned inhumane jail conditions, especially chain gangs, and the routine commitment of all insane persons.

FIFTY YEARS AGO

✿ [JULY, 1950] ✿

This issue featured two papers presented at the 139th annual meeting of the Rhode Island Medical Society. John J. Morton, MD, Professor of Surgery, University of Rochester School of Medicine and Dentistry, discussed "Diverticulitis and Cancer of the Colon." John J. Poutas, MD, Medical Director, Lever Brothers Co., discussed "Industrial Medicine and the Private Practitioner."

In a paper presented before the Providence Medical Association, Charles E. Millard, MD, (president, Rhode Island Academy of General Practice), discussed "The Problems of General Practice and Their Solutions." Because 80% of the practice of medicine was in the hands of general practitioners, Dr. Millard called for "restoring the family physician to a position commensurate with his contribution to society." Also, he praised family physicians as "the profession's greatest bulwark against socialized medicine."

Governor Pastore had turned a valve to divert the daily flow of 4 million gallons of raw sewage from Bucklin Brook into a modern treatment system. An Editorial on Pollution lauded this "good start."

A Committee reported on use of the library, which received 243 periodicals last year. On an average day, 20-30 callers contacted the library. Last year the library logged 2390 visitors (390 more than the previous year); almost half were physicians.

TWENTY FIVE YEARS AGO

✿ [JULY, 1975] ✿

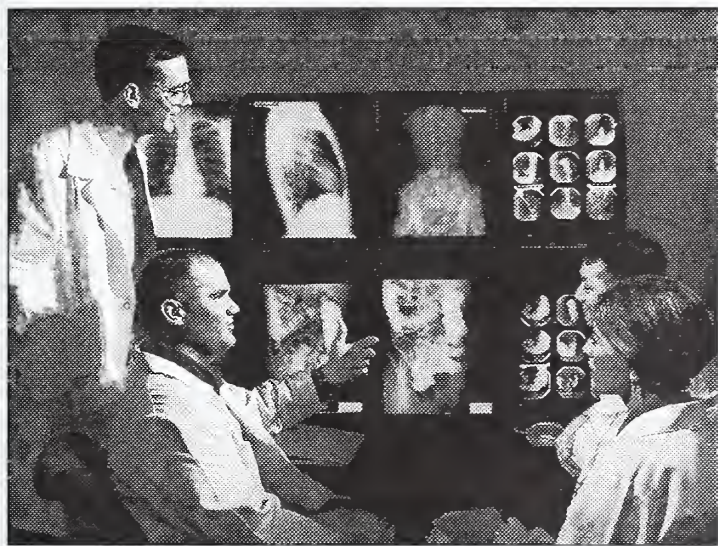
Rhode Island Medical Society President Stephen J. Hoye, RMD, in "Malpractice - the Patient Pays!!" reported that each member would be assessed \$50 to pay for advertisements, part of a statewide campaign launched by "YOU - THROUGH YOUR PATIENTS! - to emphasize that...this ...is a health care cost which can and must be restrained and, hopefully, reduced."

Edwin N. Forman, MD, in "Lymphomas in Children," reported, "Long-term Remissions are common in both Hodgkins and non-Hodgkins Lymphoma with newer treatment regimens."

Arnold Porter, MD, in "Blue Shield - Fifteen Years," (an address given at the annual meeting of the corporation of Blue Shield), summed up major legislation over his past decade as chairman of the board, including Medicare, PSRO legislation; Health Planning and Resources Development Act of 1974.

Charles L. Hill, MD, described the "Ambulatory Surgical Facility," as a concept consistent with cost containment and quality of care.

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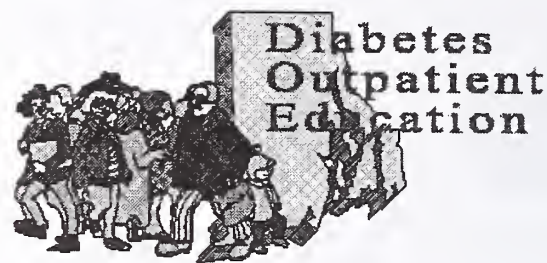
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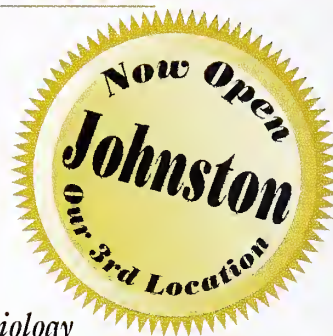
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This issue, with the insert, "Instructions for the Reporting of Communicable, Environmental and Occupational Diseases by Physicians, Laboratories and Health Care Facilities," is being sent to all physicians in the state, under a Bioterrorism Preparedness grant from the Centers for Disease Control and Prevention.

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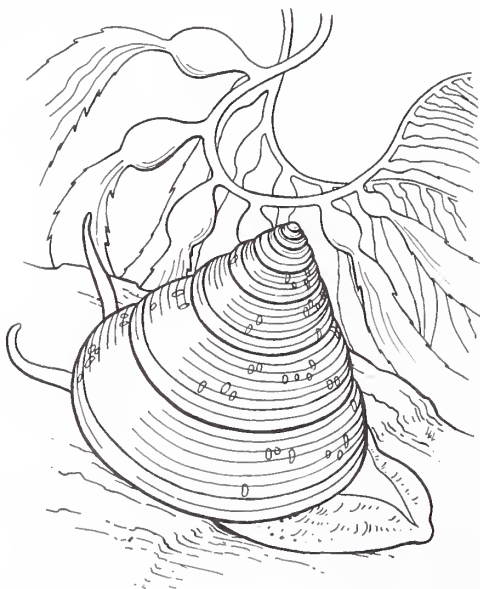
Evidence-Based Medicine & Medical Myths

"You can fool too many of the people too much of the time."

— James Thurber

In this issue of *Medicine & Health/Rhode Island* we introduce a new column, "Myths in Medicine." Readers are invited to submit articles describing a commonly believed medical myth they would either like to debunk themselves or bring to my attention so that I can have an expert take on the task of debunking it. The idea for this arose from a chapter devoted to medical myths in an excellent new introductory book on evidence-based medicine, *Evidence-Based Clinical Practice Concepts and Approaches* by Geyman, Deyo & Ramsey.

The term "EBM" has intrigued me for a long time. I was never exactly sure what EBM was and always felt a bit embarrassed to ask, assuming that everyone else knew what it meant. In addition, the notion that EBM was simply the practice of medicine based on evidence and that the study of this topic was simply the study of data analysis and decision-making seemed a bit too naïve and obvious. It must, I reasoned, reflect



something a bit more obscure. After I read this book I realized that as simple as the concept of EBM is, its practice is more difficult. As the chapter on medical myths brought home to me, we in medicine, especially its teachers, often pay more lip service than brain service to much of our decision-making. I was astounded to learn that: vitamin B12 can be given orally; propranolol does not induce depression; sliding insulin scales are not useful; corneal abrasions heal faster without patching.

These are some of the myths this journal will explore and explode in coming months.

But is EBM a new field or even a field of study at all? Is it not simply a guiding principle, that medical decision-making should, where possible, balance what is known and not known, in terms of benefits, risks and costs?

Evidence-based medicine has been defined as the "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."^{1,2} Use of the term reminds me of the fictional character who was surprised and proud to learn that he'd been talking in prose all his life. I think that most of us, if not all of us, try to carry out this principle in our routine practice, sometimes modifying it by the vagaries of patient expectations and the need to balance these with outcomes. But EBM also includes: systematic rather than casual searching for evidence; reviewing evidence critically, using the principles of clinical epidemiology; trying to balance benefits and adverse effects for individual patients.

My own impression is that EBM

is actually another term for "skeptical" medicine. It is a highly refined process rather than an actual branch of clinical medicine that tries to throw the searchlight of data and reasoning on what is too often an application of "received wisdom." Medicine is part art.

One can learn the scientific principles, the data concerning clinical trials, and a huge amount of relevant data, but if one can't obtain a good history, perform a reliable examination and develop a reasonable rapport with the patient and family, the huge database is irrelevant. On the other hand, one can obtain a good history and exam, develop rapport and not know how to choose the best test or treatment.

EBM usually steps in at the decision-making end, after a diagnosis is made and a decision on treatment must follow, or when a symptom requires a diagnostic study but one might be more useful or less expensive than another. But EBM also assesses parts of the history or exam. For example, there is a persistent myth that a carotid bruit has some significance for cerebrovascular disease (another myth scheduled for destruction here).

Increasing attention is being paid to EBM in all medical fields. The American Academy of Neurology, for example, has established clinical practice guidelines and assessments for guiding some decision-making, establishing grades of certainty to their assessments. A new treatment may be endorsed as having shown clear efficacy in multiple reliable trials, or a treatment or diagnostic test has been shown to be useless (e.g. EEG in the evaluation of headache), or a treat-



ment or diagnostic test has been shown promising but cannot yet be endorsed, etc. While these assessments are often equivocal, they outline what is known, what is not known and why there is equivocation.

This stands in contrast to the legalistic concept of "standards of care," which may represent an outdated but still "accepted" approach to a problem (see the medical myths column for examples). Just because "everyone does it" doesn't make it correct.

These assessments and EBM are important in general for counteracting our tendency to practice what we were taught, even though we know medicine has changed mightily. It has been reported that the single greatest source of continuing medical education for doctors is the pharmaceutical

industry, particularly via drug representatives, but also with sponsored lectures, including restaurant and weekend "informercials." Drug reps don't lie but they may mislead. As the old saying goes, "statistics don't lie but you can lie with statistics." The effectiveness of one new drug I use is supported by two, well-performed trials. The benefits were minor but definite. I was surprised to recently learn that a third trial, described in the package insert, was negative. Unfortunately, it wasn't published so I hadn't known about it. An EBM-based approach to this drug's assessment would raise the skeptic's warning flag.

One major target of EBM is the pattern of doing what an authority recommends without knowing the data and the rationale. A colleague

once announced, "Don't confuse me with data. Just tell me what to do." There are some targets EBM won't hit, but for the rest of us, skepticism, within reason (and with reason) is a virtue we must always hold dear, whether we call it EBM or not.

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2. Sackett DL, Rosenbert WM, Gray JA, et al. Evidence based medicine: What it is and what it isn't. *BMJ* 1996;312:71-2.

— Joseph H. Friedman, MD

A Bloody Path from Buckingham Palace to St. Petersburg

From Dr. John Snow's clinical records: "Thursday, 7 April 1853. Administered chloroform to the Queen in her confinement . . . I commenced to give a little chloroform with each pain, by pouring about 15 minims by measure on a folded handkerchief. Her Majesty expressed great relief. The infant was born and the Queen appeared very cheerful and well."

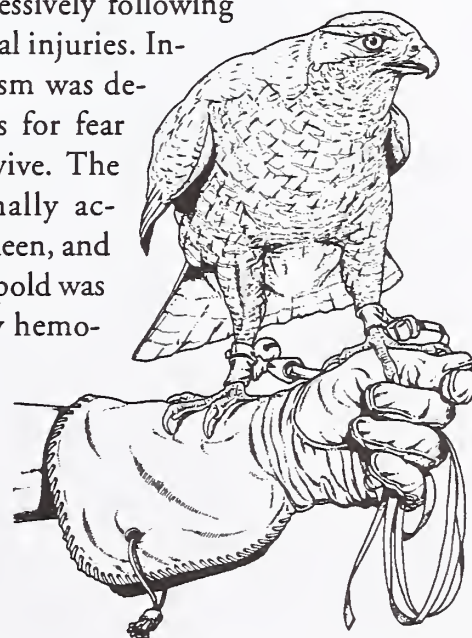
When Queen Victoria allowed the delivery of her infant son to be eased by this anesthetic, she acted in conscious defiance of the prevailing theological view that women must abide by the Scriptural admonition: "In sorrow thou shalt bring forth children" [Genesis 3:16.] Many English clergy were incensed that the royal family had tolerated the use of an agent, contrived by humans, to abort the pains of childbirth. And many a Sunday sermon declared that a mortal sin had been committed by Queen Victoria and by those physicians who administered the medication.

The anesthesiologist so condemned was John Snow, MD, a 40 year-old London practitioner and England's leading authority on the use of anesthetics. Inhalant anesthetics, a new form of medical intervention, were first employed in 1845 when ether allowed a major surgical operation to be performed in Massachusetts General Hospital. Anesthetics, when used to ease the pains of childbirth, however, were widely viewed with profound suspicion as a trespass upon divine authority. Despite these views, a new anesthetic agent called chloroform was introduced in 1847 by Dr. James Young Simpson, Scotland's

leading obstetrician.

About six months after Queen Victoria had been anesthetized, Snow was summoned by the Archbishop of Canterbury, the Church of England's leading cleric, to provide chloroform anesthesia for his daughter. And on October 20, 1853, Snow's anesthesia helped the Archbishop's daughter be delivered of a healthy baby son. This event, more than the Queen's sanction of chloroform, subdued much of the ecclesiastic criticism of obstetrical analgesia.

The story of Queen Victoria's chloroform-aided maternity confinement has further ramifications. The baby, born on April 7, 1853, was Prince Leopold, Victoria's eighth offspring and fourth son. He was a sickly infant, inclined to bleed excessively following the slightest of physical injuries. Indeed, his royal baptism was delayed by five months for fear that he might not survive. The court physicians finally acknowledged to the Queen, and to the world, that Leopold was a victim of hereditary hemophilia. The newspapers of London were quick to associate the Prince's perilous state with the heathen use of chloroform. The



hemophilia, they conjectured, was palpable evidence of divine retribution.

Prince Leopold grew to maturity despite repeated bleeding episodes following minor injury. At age 31, while in Cannes, France, a trivial blow to his head resulted in a massive intracranial hemorrhage and death.

Hemophilia is a recessive hereditary disease caused by a defect upon the X chromosome. The curious pattern of hereditary transmission of this disease [female carriers of the trait, male victims] was first described in detail by Dr. Christian Nasse, of Bonn, in 1820. There was no evident hemophilia in Victoria's past and so geneticists presume that a mutation had taken place in the generation preceding Victoria's.

Inherited disorders of the X chromosome are transmitted in a skewed fashion. The mother carrying the chromosomal change is not herself clinically affected, but about one half of her male offspring will be hemophiliacs and about one half of her daughters, although clinically normal, will convey the bleeding defect to about half of their male offspring.

Queen Victoria had nine children. One of her sons, Leopold, was a clinically apparent victim of hemophilia. And three of her daughters, as evidenced by the appearance of hemophilia in their male offspring [ie, the grandsons of Victoria], were carriers of the mortal trait. One daughter, Beatrice, who married the German Prince Henry of Battenberg, had two sons with overt hemophilia and one daughter, who later married Alphonso XII, King of Spain. They, in turn, had four sons, two of whom [Victoria's great-grandsons] developed hemophilia. There was Alphonso who died at age 31 following a minor car accident; and his brother, Gonzalo, who also bled to death at age 20 after a trivial car accident.



Yet another daughter of Victoria, Alice, married Louis IV of Hesse-Darmstadt. One of her two sons died of hemophilia at age 3. She also bore five daughters, two of whom were hemophilia carriers. One of these daughters, Alix by name, married Nicholas Romanov, shortly to be Nicholas II, Tsar of Russia. She changed her name to Alexandra, converted to the Russian Orthodox faith and bore Nicholas five children: four daughters and a frail son named Alexis who, as Tsarevich, was to inherit the Romanov throne. But Alexis was hemophiliac and bled profusely following the most trivial of injuries.

The year was 1907 and physicians knew no way of suppressing the bleeding tendencies of hemophilia. In desperation Tsarina Alexandra sought the help of mystics of many nations. An itinerant, illiterate monk from Siberia, Grigori Yefimovich, appeared in St. Petersburg and claimed that only his intervention could stay the bleeding of the tsarevich. The bleeding did halt and Alexandra then became convinced that her son's continuing survival rested solely upon the monk's prayers. During the next few years the monk [called Rasputin, a Russian word meaning debaucher] became the guardian of Alexis while exerting substantive control of a deteriorating Russian government.

In 1916, many of the senior nobility of Russia arranged for Rasputin's assassination. And on July 18, 1918, the Tsar, his wife Alexandra, his four daughters [Olga, Tatiana, Marie and Anastasia] and the Tsarevich Alexis were summarily executed by the Bolsheviks in the Urals city of Ekaterinburg.

Queen Victoria, ruler of the world's most extensive empire, was powerless before the lethal potential of hemophilia afflicting her son, grandsons and even great-grandsons. The mutant gene initially transmitted by Victoria ultimately tainted the royal families of Germany, England, Spain and Russia.

Hemophiliacs are no longer at the mercy of random injury since effective replacement therapies are now available. And chloroform has been supplanted by even safer, more efficient forms of childbirth analgesia. Relatively painless deliveries no longer elicit polemics from the pulpits. Yet history moves in curious paths, establishing outlandish connections between personages as widely separated as James Y. Simpson, Queen Victoria, and even Rasputin.

— Stanley M. Aronson, MD

Brown University School of Medicine: Class of 2000

Stephen R. Smith, MD, MPH, Alexandra Morang, Hilary Sweigart, Janice Viticone

On May 29, 2000, 81 men and women received the Doctor of Medicine degree from Brown University, representing the 26th class of physicians graduated from that institution since 1975. If this class follows the pattern of preceding classes, approximately 14% will eventually enter the practice of medicine in the State of Rhode Island. Of the 1823 physician graduates of previous classes, approximately 232 (13%) are currently licensed to practice in Rhode Island.

The purpose of this article is to introduce the graduates of the MD Class of 2000 to the physician community in Rhode Island, as many will be your future professional colleagues.

A PORTRAIT OF THE CLASS OF '00

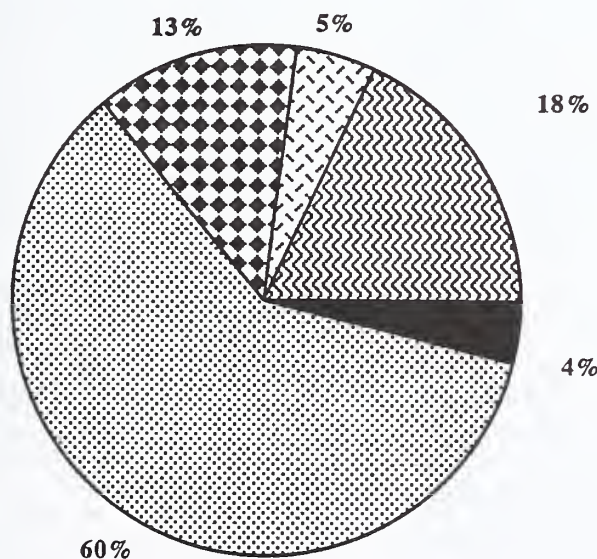
Thirty-nine graduates were men (48%) and 42 were women (52%). The racial/ethnic composition of the class (Table 1) again shows a slightly higher proportion of students from Asian American backgrounds (46%) than the previous year. (Over a third of the students in the first four undergraduate years of the eight-year Program in Liberal Medical Education [PLME] are Asian American.) Sixteen percent of the graduates are members of minority groups underrepresented in medicine (8 African Americans, 3 mainland Puerto Ricans, and 2 Mexican Americans) as defined by the As-

Abbreviations Used:

AAMC	Association of American Medical Colleges
EIP	Early Identification Program
PLME	Program in Liberal Medical Education
URM	underrepresented minorities

sociation of American Medical Colleges (AAMC). This number is considerably higher than the 7% underrepresented minorities (URM) reported for last year's graduates. For the past five years, about 20% of freshmen college PLME students have been from underrepresented minority groups. The percentage of underrepresented minority students in

Figure 1
Specialty Choices of the
Brown University School of Medicine
Class of 2000



Psychiatry	Primary Care
Surgical Specialties	Emergency Medicine
Other	

Table 1. Demographic Characteristics of the M.D. Graduates of the Brown University School of Medicine Class of 2000

Sex			
Male	39	48%	
Female	42	52%	
Race			
White	30	37%	
Asian American	37	46%	
African American	8	10%	
Mexican American	2	2%	
Puerto Rican	3	4%	
Foreign National	1	1%	
State of Residence			
New York	15	19%	
Rhode Island	12	15%	
California	11	14%	
New Jersey	9	11%	
Mississippi	4	5%	
Pennsylvania	3	4%	
Massachusetts	3	4%	
Illinois	3	4%	
Connecticut	3	4%	
Missouri	2	2%	
Maryland	2	2%	
Indiana	2	2%	
Florida	2	2%	
Other States	8	10%	
Other Countries	2	2%	

the first three years of the medical school is 15%.

Twelve graduates are residents of Rhode Island. The Rhode Island students in this year's graduating class came from eight communities in the state: five from Providence, one each from Ashaway, Barrington, Cranston, Greenville, Hope Valley, Newport, and Portsmouth. The high schools from which the students graduated also reflect this diversity, with students having attended Barrington, Bishop Connelly, Chariho, Classical, Cranston West, Groton, LaSalle, Lincoln, Portsmouth, and St. George's.

The MD Class of 2000 reflects the growing proportion of students from the PLME, with 55 such graduates (68%) having come through that route. The second largest cohort of students (16 graduates) came through the combined Brown-Dartmouth Medical Education Program in which students spend their first two years of medical school at Dartmouth, then transfer to

Brown for the final two years.

The medical school entered into special agreements with postbaccalaureate premedical programs at Bryn Mawr College and Columbia University shortly after the PLME was inaugurated. Students from these programs decided upon a career in medicine only after completing college. Typically, they have been engaged in other careers for several years following college. The goals in establishing this new route of admission were to maintain a rich diversity in the student body by admitting students who were older and who had different academic and life experiences as well as rounding out the total class size to compensate for the expected attrition from the PLME. One member of the class was a postbaccalaureate student who came through Bryn Mawr College.

Among the remainder of the class, six students were part of the Early Identification Program (EIP), one each from Providence College and the Uni-

versity of Rhode Island, and four from Tougaloo College. EIP students are offered provisional admission to the medical school during their sophomore year at their respective undergraduate colleges. Of the remaining graduates, two entered medical school through the MD/PhD program, and one through advanced transfer.

Brown University was the most common undergraduate college among the graduates accounting for 59 graduates. Tougaloo College was second with four members from the Class of 2000.

The most common undergraduate major (46%) among the class members was biology (including subdisciplines such as neural sciences and microbiology). Science majors taken together (including psychology) accounted for 69% of all majors, while 19% majored in the humanities and 17% in the social sciences. (Total is more than 100% due to double majors.) Among the humanities majors, English was the most common choice,

Table 2. Specialty Choices for MD Classes of 1996-00, Brown University School of Medicine

Specialty Choice	1996 No.	%	1997 No.	%	1998 No.	%	1999 No.	%	2000 No.	%
Primary Care, Total	53	60%	52	59%	46	61%	45	53%	49	60%
Internal Medicine, Total	25	28%	16	18%	18	24%	16	19%	19	23%
Categorical Medicine	18	20%	11	13%	13	17%	14	16%	18	22%
Primary Care	7	8%	5	6%	5	7%	2	2%	1	1%
Pediatrics	10	11%	10	11%	14	18%	7	8%	12	15%
Family Medicine	13	15%	18	20%	10	13%	12	14%	10	12%
Medicine/Pediatrics	1	1%	3	3%	1	1%	2	2%	2	2%
Obstetrics & Gynecology	4	5%	5	6%	3	4%	8	9%	6	7%
Surgery	4	5%	6	7%	5	7%	7	8%	3	4%
Surgical Subspecialties, Total	8	9%	10	11%	6	8%	9	11%	7	9%
Ophthalmology	2	2%	2	2%	2	3%	2	2%	1	1%
Orthopedics	4	5%	4	5%	1	1%	3	4%	2	2%
Neurosurgery	0	0%	1	1%	0	0%	1	1%	3	4%
Urology	0	0%	0	0%	1	1%	2	2%	0	0%
Plastic Surgery	1	1%	2	2%	2	3%	1	1%	1	1%
Otorhinolaryngology	1	1%	1	1%	0	0%	0	0%	0	0%
Dermatology*			1	1%	1	1%	1	1%	1	1%
Emergency Medicine	3	3%	9	10%	5	7%	4	5%	4	5%
Psychiatry	2	2%	3	3%	2	3%	6	7%	3	4%
Neurology	4	5%	2	2%	1	1%	2	2%	1	1%
Transitional & Preliminary Medicine	6	7%	0	0%	1	1%	1	1%	1	1%
Institutional Specialties, Total	2	2%	5	6%	5	7%	6	7%	10	12%
Anesthesiology	0	0%	1	1%	1	1%	0	0%	1	1%
Pathology	1	1%	0	0%	0	0%	1	1%	0	0%
Rehabilitation Medicine	1	1%	0	0%	0	0%	0	0%	0	0%
Radiology & Radiation Oncology	0	0%	4	5%	4	5%	5	6%	9	11%
Delaying Residency	6	7%	0	0%	4	5%	4	5%	2	2%
Totals	88	100%	88	100%	76	100%	85	100%	81	100%

*Prior to 1997 first-year match in dermatology not possible

**Table 3. Brown University School Of Medicine
Class Of 2000 Residency Positions**

NAME OF GRADUATE	HOSPITAL NAME/MEDICAL SCHOOL AFFILIATION	SPECIALTY
Andrea Anderson	Harbor-UCLA Medical Center	Family Practice
Kavita Babu	Rhode Island Hospital/Brown University	Emergency Medicine
Brook Beall	Boston University Medical Center	Medicine-Prelim
	Boston University Medical Center	Emergency Medicine
Carolyn Boltin	Mt. Sinai School of Medicine(NY)-Cabrini	Medicine Prelim
	Rhode Island Hospital/Brown University	Radiology
Stephen Cha	Einstein/Montefiore	Medicine
Albert Chang	UCLA Medical Center	Medicine
James Chen	Brown University Internal Medicine Residency	Medicine-Prelim
	St. Vincent's Hospital(MA)	Radiation
Rochelle Chodock	University of Texas Medical School-Houston	Surgery
Michelle Cicilline	Franklin Square Hospital(MD)	Family Practice
Stephen Cobery	Bethesda Naval Hospital, Maryland	Surgery-Prelim
	Brown University	Neurosurgery
Valerie Danielson	Tacoma Family Medicine	Family Practice
Quinn Dinh	Beth Israel Medical Center	Ob/Gyn
Jamie Dwyer	Mayo Graduate School of Medicine/Florida	Medicine
Gregory Fauteux	Brown University Internal Medicine Residency	Medicine-Prelim
Angel Ferrer	UMDNJ-New Jersey-Newark	Pediatrics
Danielle Garner	Spartanburg Regional Health(SC)	Family Practice
Gretchen Green	Brown University Internal Medicine Residency	Medicine-Prelim
	Yale-New Haven Hospital	Radiology
Nichole Green	University of Alabama Hospital-Birmingham	Pediatrics
Melanie Greenan	Beth Israel-Deaconess Medical Center	Medicine
Samuel Gurevich	Yale-New Haven Hospital	Medicine-Primary
Juliette Gustin	Maine Medical Center	Pediatrics
Jason Hann-Deschaine	Thomas Jefferson University/Dupont Children's	Pediatrics
Kathleen Hogan	Rhode Island Hospital/Brown University	Surgery-Prelim
Raymond Hong	NYU Downtown Hospital	Medicine-Prelim
	North Shore University-Manhasset	Radiology
Jill Hoprasart	William Beaumont Hospital(MI)	Ob/Gyn
David Hou	Brown University Internal Medicine Residency	Medicine-Prelim
	Rhode Island Hospital/Brown University	Radiology
Wendy Huang	NYU Medical Center	Emergency Medicine
David Jackman	Beth Israel/Deaconess Medical Center	Medicine
Shuba Kamath	Mt. Sinai Hospital(NY)	Pediatrics-Primary
Sarasa Kimata	Temple University Hospital	Medicine
Michael Klein	University North Carolina Hospital	Family Practice
Anne Ko	Mt. Sinai School of Medicine(NY)-Cabrini	Medicine-Prelim
	New York Eye & Ear Infirmary	Ophthalmology
Eli Kramer	Baystate Medical Center(MA)	Medicine
Richard Lavi	MetroHealth Medical Center(OH)	Med/Peds
Jane Li	University of Massachusetts Medical School	Family Practice
Lenny Lu	McGaw Medical Center/Northwestern University	Plastic Surgery
Sharon Malcolm	Roger Williams Hospital	Medicine
Michele Mathieu	Rhode Island Hospital/Brown University	Pediatrics
Edward Maxwell	University of California-San Francisco	Psychiatry
Jennifer Mbuthia	Tripler Army Hospital, Hawaii	Pediatrics
Lisa Menard	Hunterdon Medical Center(NJ)	Family Practice
Sanjay Naik	NYU Medical Center	Medicine
Imran Omar	MacNeal Hospital(IL)	Transitional
	Thomas Jefferson University(PA)	Radiology
Julie Pan	McGaw Medical Center-Northwestern University	Psych
Joel Park	Rhode Island Hospital/Brown University	Med/Peds
Michael Passero	Boston University Medical Center	Medicine
Maitri Patel	Harvard Longwood	Psychiatry
Rick Quiles	Nassau County Medical Center	Pediatrics
Erica Quinn	University Hospital-Jackson(MS)	Family Practice
Michelle Quogue	Kaiser Permanente(Los Angeles)	Family Practice
Fred Randolph	Hospital of the University of Pennsylvania	Emergency Medicine
Sandhya Rao	University of Massachusetts Medical School	Ob/Gyn

(cont.)

**Table 3. (cont.) Brown University School Of Medicine
Class Of 2000 Residency Positions**

NAME OF GRADUATE	HOSPITAL NAME/MEDICAL SCHOOL AFFILIATION	SPECIALTY
Seth Rosen	Mt. Sinai Hospital(NY)	Medicine
Lenore Saulsberry	Tuscaloosa Family Practice	Family Practice
Joshua Schiffman	Stanford University	Pediatrics
Heather Schlott	Dartmouth-Hitchcock	Pediatrics
Charles Shen	Bridgeport Hospital	Radiology
John Shen	Brown University Internal Medicine Residency	Medicine-Prelim
	Roger Williams Hospital	Dermatology
Teena Shetty	St. Elizabeth's Medical Center(MA)	Medicine-Prelim
	New York Hospital/Cornell University	Neurology
Lewis Shin	Winthrop University Hospital(NY)	Medicine-Prelim
	Winthrop University Hospital(NY)	Radiology
Robert Shin	NYU Medical Center/Hospital for Joint Diseases	Orthopedic Surgery
Suzanne Strubel-Lagan	Women & Infants Hospital/Brown University	Ob/Gyn
Nana Tchabo	Georgetown University Hospital	Ob/Gyn
Michael Tobias	Einstein/Montefiore	Surgery-Prelim
	Einstein/Montefiore	Neurosurgery
Andrea Tom	Santa Clara Valley Medical Center(CA)	Medicine
Nhan Tran	Beth Israel/Deaconess Medical Center	Medicine-Prelim
Kavita Vijayaraghavan	Johns Hopkins Hospital	Medicine
Anjali Viswanathan	Atlanta Medical Center	Medicine
Danielle Marder Walker	NYU Medical Center	Medicine-Primary
Eric Walsh	Rhode Island Hospital/Brown University	Orthopedic Surgery
Selvi Williams	Beth Israel/Deaconess Medical Center	Medicine
Tony Wong	Kaiser-Permanente-Oakland	Medicine
Serena Wu	University of Chicago	Ob/Gyn
Annoel Yabes	Kaiser-Permanente-Oakland	Medicine
Jeannie Yang	University of Wisconsin Hospital/Clinics	Surgery
Carmela Yarlagadda	University of Texas Southwest Medical School-Dallas	Pediatrics
Vamsi Yarlagadda	University of Texas Southwest Medical School-Dallas	Pediatrics
Kevin Yeh	Lahey Clinic(MA)	Medicine
Vasilios Zerris	New England Medical Center/Tufts University	Surgery-Prelim
	New England Medical Center/Tufts University	Neurosurgery

while political science was the most popular choice among those majoring in the social sciences

WHERE THEY ARE GOING

Internal medicine remained the most popular specialty (19 graduates); pediatrics placed second (12 graduates). The number of graduates going into diagnostic radiology (11%) was unusually high this year. Nationally, only about 3% of graduates enter this specialty. Table 2 lists the number of students selecting different types of residency programs.

The proportion of the class entering specialties in primary care increased to 60% of the class from 53% in the previous year. This includes the fields of internal medicine, pediatrics, family practice, medicine/pediatrics, and obstetrics and gynecology. Figure 1 illustrates the specialty choices of the

Class of 2000.

The actual number of graduates who will eventually practice primary care after completing their graduate medical education training will be smaller than the 60% reported here, if the past is any indication. An analysis of longitudinal data collected by the AAMC of the graduates of the classes of 1987-1991 reveals that over half of the graduates who enter residency programs in internal medicine end up in a subspecialty of internal medicine, such as cardiology, as will about a quarter of those entering residency training in pediatrics.

The data for Brown graduates are similar to the national AAMC longitudinal study data. Of those Brown graduates in the MD classes of 1987-1991, only 46% of those entering residencies in internal medicine actually went into general internal medicine

practice. In pediatrics, the figure is 59%. Among the primary care residencies, only family practice does not exhibit this pattern. Actually, the number of graduates in those five classes who eventually enter family practice is greater than those who started out that way by about 14%. The AAMC data do not report subspecialization in obstetrics and gynecology. The Brown data show that 96% stay in the field of obstetrics and gynecology, but the proportion who subspecialize is not known. Applying this data to this class, about 34 graduates (42%) will actually practice in primary care.

The proportion of U.S. medical school graduates entering primary care specialties fell from the previous year to 51%, the lowest since 1995. For the sixth consecutive year, more than 50% of U.S. medical school seniors will pursue training in internal medicine

Table 4. Where Graduates Are Going For Residency

State	Number	Percentage
Alabama	2	2.5
California	8	10.1
Connecticut	1	1.3
District of Columbia	1	1.3
Florida	1	1.3
Georgia	1	1.3
Hawaii	1	1.3
Illinois	4	5.0
Maine	1	1.3
Maryland	3	3.7
Massachusetts	15	19.0
Michigan	1	1.3
Mississippi	1	1.3
New Hampshire	1	1.3
New Jersey	2	2.5
New York	14	17.7
North Carolina	1	1.3
Ohio	1	1.3
Pennsylvania	3	3.7
Rhode Island	11	13.9
South Carolina	1	1.3
Texas	3	3.7
Washington	1	1.3
Wisconsin	1	1.3
TOTAL	79	100%

[includes ALL students with PGY-1 positions in Class of 2000]

(25%), pediatrics (13%), and family practice (14%), according to the AAMC.¹ (The AAMC does not include obstetrics and gynecology among the primary care specialties.)

Table 3 lists the Class of 2000 graduates and where they will be doing their residency training. Of the 79 graduates who will enter residency training next year (2 are delaying their residencies for 1 or more years), 11 graduates (14%) matched with Brown-affiliated residency programs and will be staying in the state. Providence was the most popular metropolitan area for the graduates with 12 members of the class headed there. Boston and New York City were the second most popular locale, with 11 graduates each locating there.

Massachusetts is the most popular state for residency and will be the home for 15 graduates next year. New York State ranks as the second most popular state for residency training. Table 4 lists those states where the graduates will be going for their first year of residency training. A majority of the Class of 2000, 66%, will stay in the cold Northeast, up from 57% in the previous class. Thirteen percent of graduates will go to the West Coast, up slightly from 11% last year.

CONCLUSION

Brown medical school graduates seem to be bucking the tide by maintaining a strong interest in primary care, even as interest ebbs nationally.

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The Pathophysiology of Poor Teaching

Stephen R. Smith, MD, MPH

Stephen Abrahamson wrote a classic article in medical education in 1978 entitled "Diseases of the Curriculum."¹ In the same vein as Abrahamson's curriculum sclerosis, I use a medical metaphor to describe and explain the causes for poor teaching in medical schools. While Abrahamson's masterpiece focused more on the description of the diseases as a pathologist might describe the gross and microscopic specimen, I will focus more on the mechanisms of "disease," as the clinician might describe the pathophysiology of a disorder.

No department at the Brown University School of Medicine or any other medical school, for that matter, exhibits all the "signs and symptoms" described below. Indeed, many of our departments are the "picture of health" when it comes to the quality of the teaching of their faculty. What follows might be considered the "textbook" description of the full-blown disorder of poor teaching.

GENETIC CODING ERRORS

The inciting injury appears to have its origin in the nucleus of the teaching cell, that is, the department. An error in genetic coding occurs in which the departmental academic plan suffers a knock-out of its medical student teaching gene. The transcribed departmental academic plan consequently is complete except for any consideration of the medical student teaching responsibilities of the department. The rest of the genetic code remains intact, which, for the basic science department, includes the teaching responsibility for graduate students and, in most cases, the teaching responsibilities for undergraduates concentrating in that discipline. For clinical departments, the teaching responsibility for residents and fellows also remains largely unaffected. The research genes for both basic science and clinical departments are never affected.

The error in transcription of the departmental academic plan results in a translational error for the job description for faculty recruitment. The advertised position lacks any mention of medical student teaching responsibilities. The search plan likewise reflects the translational error as reflected in the journals in which the job position is advertised, all of which are highly specialized research journals.

The search plan also omits any mechanisms by which the prospective faculty member would have his or her teaching abilities judged. Thus, while the applicant is required to submit research papers for the search committee's review, no teaching evaluations must be submitted. Finalist applicants are expected to present their research findings in seminars or lectures, but are not required to actually teach medical students during their visit.

The genetic error is so complete that potentially self-correcting mechanisms are also deleted. No medical students are included in the search committee membership and the search plan is not reviewed by the associate dean for medical education.

DISORDERS OF IMPLANTATION

Having selected a faculty member based upon the genetically altered search plan, new faculty members typically lack medical student teaching receptors. This deficit could be compensated for, at least partially, if the department had in place a structured support system for new faculty to acquire teaching skills. However, this compensatory system is usually atrophic.

Compounding the problem, new faculty are recruited with the promise that they will not have to teach for the first couple of years so they can get their research firmly established. By that time, faculty members have usually established their research so well that they

are devoting twice the percentage of time to that endeavor than their research grants are paying for, thus leaving them with the feeling that they have no spare time for teaching. This makes implantation into the teaching program more difficult.

In clinical departments, service demands complicate the picture. All faculty are expected to generate enough patient revenue to maintain the high incomes that academic physicians have come to expect in the past few decades. Since third-party reimbursements have decreased per unit of service, faculty must generate more units of service to maintain net income. This means more time seeing patients unencumbered by medical students who slow faculty members down and less time for teaching.

DISORDERS OF TEACHING

Despite the faulty receptors that impair implantation in the medical school curriculum, new faculty usually do end up teaching medical students. The disease of poor teaching becomes symptomatic and observable at this point in the disease process.

One of the earliest signs of poor teaching is a form of coprolalia in which the faculty member has an uncontrollable urge to initiate communication with the students with statements like, "There is no way that I can possibly teach you all that you need to know in the ridiculously short amount of time allocated to this subject."

This is usually followed by an attempt to nevertheless present to the students all the information anyway. This takes the form of overhead slides crammed with text too small to read except for those in the first row of seats, which is whisked off the projector before even those students can transcribe more than a fraction of the contents.

Any protests that the slide went by too quickly are met with the rejoinder

der that "it's all in your textbook anyway," which, while true, makes students wonder why the lecture was necessary in the first place. The same information can be found in the 200 pages of small print assigned per class, which can be easily read by a reader of average speed in about 12 hours.

The preferred method of assessment in this disorder is some form of "objective" testing in which students must interpret poorly written test items to figure out which specific piece of minutiae the instructor wants them to recall or recognize from memory. This syndrome of force feeding of large quantities of factual information that students are supposed to be able to regurgitate on demand is known as bulimic teaching.

DIAGNOSIS

Although poor teaching is symptomatic and observable at this stage of the disease, it often goes undetected by anyone except the students. Since direct methods of monitoring, such as having more experienced teachers observe the novice teacher, are generally not considered culturally acceptable, indirect monitoring is used instead. This usually consists of teaching evaluations completed by the few students who persist in attending class instead of studying on their own. Even these data sometimes get misplaced before reaching a central data processing location.

Once entered into a computer statistical program approximately three months later, the teacher will receive a report consisting of numbers to the tenth of a point beside an integer, such as "1. 2.9." A separate sheet will sometimes accompany the data report indicating what teaching skill the number "1" relates to, such as organization, and what the rating scale is (1=poor, 5=excellent). Thus, the faculty member learns that his or her organization is a 2.9.

Oftentimes, this is as far as the data get. The data are available to the department chairman who only needs to go the office where the data are kept in the medical school administrative offices and request to see the figures.

At that point the department chairman will also know that the new faculty member's organization is a 2.9.

How good or bad is 2.9? Unlike a serum creatinine, teaching ratings do not have a range of normal. Obviously, it's not poor, since that would be a 1.0. Okay, so it's not excellent, but this is the faculty member's first year of teaching. Perhaps the department chairman may suggest to the instructor that he or she should try to work on organization. Unfortunately, the faculty member may be clueless on what should or could be done, because if the instructor understood what excellent or even good organization was in the first place, he or she would have done that. Thus, the feedback mechanisms that might be able to ameliorate poor teaching are dysfunctional as well. The feedback signal is too weak and nonspecific to produce a useful effect.

This syndrome of force feeding of large quantities of factual information that students are supposed to be able to regurgitate on demand is known as bulimic teaching.



MANAGEMENT

Conservative interventions to improve the condition are often of limited value. The patient is often in a state of denial. Few incentives exist to motivate change in behavior. Indeed, the new faculty member is often warned not to put too much time or effort into teaching because that will only detract from the things that are really important for career advancement, namely research.

When confronted with irrefutable evidence of student dissatisfaction, poorly rated instructors will often react defensively, saying that students don't like them because they maintain high standards and don't pander to the

students or spoon-feed them. Sometimes they will add their dismay at how the students at this institution seem spoiled and poorly prepared. They should not be expected to provide remedial teaching to students who lack the necessary background for their course.

When conservative therapy fails, more radical therapy carries significant risk and only remote promise of success. This consists of surgically removing poor teachers from the teaching program. While this may remove the immediate lesion, it does nothing to change the underlying disease process. Surgical removal creates its own problems, leaving a void in the tissue that is not easily filled. It often creates inflammation in the affected department directed at the force that caused the removal. This results in a scar that may not be much better than the preoperative status of the teaching situation. Either someone else in the department must replace the excised teacher, which is accepted only reluctantly, or large sums of money must be spent to hire adjunct faculty to do the job. Of course, these additional funds must come from the dean's office, not from the department's budget.

Oftentimes, the excised faculty member is removed only from the medical student teaching program, but remains in the department, now freed to devote more time to more important matters. In those cases where the faculty member is not retained in the department, the cycle begins again, only to repeat the same dysfunctional patterns.

STRATEGIES FOR CHANGE

The tongue-in-cheek medical metaphor contains enough elements of truth to suggest ways that could improve teaching. First and foremost, the academic plans of departments must recognize the importance of their medical student teaching responsibilities and assign to it the same high priority given to research and, in the case of clinical departments, clinical service.

This priority should be reflected in faculty search plans. The expected teaching responsibility should be

prominently described and placed before research and service responsibilities. Advertisements should specify that applicants should have a demonstrated track record of excellence in teaching. Advertisements should be placed in professional journals of a general nature that are likely to be read by prospective candidates who have an interest in teaching as well as research. Candidates' résumés should be carefully reviewed for evidence of teaching experience and teaching evaluations should be requested. Candidates who are invited for interviews should be asked about their teaching activities, their philosophy of teaching, and their approach to teaching, especially their approach to students who are having difficulty. They should be invited to teach while on campus, if this is practical.

Not all faculty recruitments need to be or should be conducted with teaching as the highest priority. On the other hand, neither should all faculty recruitments be focused on the research or service goals of the department. An appropriate balance needs to be achieved. This has not been the case despite the indisputable fact that teaching medical students is the only unique function of medical schools and should be their primary mission.

New faculty need to be encouraged and supported in their teaching role. They should be assigned to a more experienced and skilled teacher-mentor. In this relationship, the new faculty member should feel safe to discuss specific teaching goals with the mentor, who can provide a friendly critique and coaching. New faculty should be given release time to participate in teacher development programs, and their participation in such programs should be required.

Teaching evaluations need to be helpful to the teacher; mere numbers won't suffice. Student evaluations need to include specific and detailed comments. All faculty, but especially new faculty, should be encouraged to obtain student feedback midway through their course of instruction, not just at the end. This allows the faculty to make midcourse adjustments and try out al-

ternative methods immediately rather than waiting until the following teaching cycle. Faculty should request that their mentors, course leaders, or consultants from the teacher development program, like the Harriet W. Sheridan Center for Teaching and Learning at Brown University, sit in on classes to observe their teaching and offer feedback. Faculty who undertake such a program should be awarded certificates of completion. Promotion committees should expect that new faculty have such certificates as part of their promotion dossier; its absence should be a matter of serious import in promotion decisions.

Promotion committees must treat teaching excellence and scholarship with the same rigor and seriousness with which they treat research excellence and scholarship. Many medical schools, including Brown, now have separate tracks for academic promotion for teacher-scholars and research-scholars. Yet faculty remain skeptical that their teaching efforts will be afforded the same consideration as the number of their research publications. I believe that faculty who are truly excellent teachers and who contribute to the scholarship of teaching do get promoted and this fact should be widely disseminated. However, I believe also that faculty who are poor teachers also get promoted and this sends the wrong message. All full-time academic faculty must be held to a standard of being good, if not excellent, teachers, just as all faculty are required to be scholars as well as teachers. Promoting bad teachers simply because they are excellent researchers or highly productive clinicians is as inappropriate as promoting excellent teachers who are not also competent scholars.

Finally, good teaching needs to be supported with adequate resources. Just as faculty demand and receive protected time to engage in research, so, too, must faculty be given protected time for their teaching. This boils down to money. Medical schools must be willing to channel financial resources to support teaching in the core curriculum. Reciprocally, faculty must be held accountable for their teaching respon-

sibilities. Better systems need to be developed to document teaching quantity and quality at the medical student level.

The pathophysiology of poor teaching is well understood. The therapeutic interventions that offer reasonable hope for improvement are also available. All we need is the determination to act.

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The Practicing Physicians of Rhode Island: Medical Schools Attended

Nikki Samaras Deary, Robert J. Sullivan, Jr., Milton W. Hamolsky, MD, Stanley M. Aronson, MD, MPH

From time to time, the Rhode Island Board of Medical Licensure & Discipline [BMLD] issues reports providing the readership of this journal with demographic profiles concerning the licensed physicians of Rhode Island.¹⁻⁹ The present report summarizes the medical schools attended by 4,578 licensed allopathic physicians of this state, garnered from the computer listing since 1991.

SOURCE OF INFORMATION

The BMLD maintains a data base on each of the licensed physicians in Rhode Island accessible through the Internet¹⁰; and amongst the items so gathered for each licensee are the name [and location] of the medical school attended and the years that the degree of MD [or its equivalent] were granted.

Records on 4,578 physicians are included in this data base. This group also includes many physicians who have retired, reached emeritus status, or died during the past decade; in addition, there are others who currently still hold Rhode Island medical licenses but who limit their medical practice to states other than Rhode Island. Only an estimated 2,900 of these 4,578 physicians are currently active practitioners within the state of Rhode Island. By using the broader data base of 4,578, the authors believe that they might

portray more accurately the patterns - and trends - of formal medical education undertaken by this state's allopathic physicians.

The 4,578 physicians were separated into four categories: female physicians granted the MD degree on or before 1970 [118]; male physicians granted the MD degree on or before 1970 [1,132]; female physicians granted the MD degree on or after 1971 [981]; and male physicians granted the MD degree on or after 1971 [2,347].

The United States and Canada possess 143 medical schools; and graduates of 123 of these schools of medicine currently hold licenses to practice medicine in Rhode Island.



Much of the information concerning the status of medical schools in nations other than the United States and Canada was derived from periodicals is-

Abbreviations Used:

BMLD Board of Medical Licensure & Discipline
WHO World Health Organization

sued by the World Health Organization [WHO], a division of the United Nations, based in Geneva, Switzerland.¹¹

FINDINGS

Table 1 summarizes the location of the attended medical schools according to the four categories described above. The majority of local practitioners [79.2%] received their formal medical education in United States schools of medicine. An additional 2.2% received their degrees from Canadian institutions. The remaining 18.6% are graduates of medical schools outside of the United States, situated in one or another of the six inhabited continents.

Table 2 provides the numbers of Rhode Island physicians [1,162] attending one of the nine accredited medical schools of New England. These nine schools, on average, graduate 934 physicians annually. Of the 268 physicians who obtained their MD degree from a New England medical school on or before 1970, three medical schools dominated: Tufts [with 45.9% of the older New England graduates], Harvard [with 19.4%], and Boston University [with 19.0%]. The medical schools at Brown, University of Connecticut and University of Massachusetts had not as yet graduated their first classes in 1970. When all of the New England-trained MDs are considered, including those with medical degrees granted after 1970, Brown graduates predominate amongst the licensed physicians of this state, accounting for 28.1%; Tufts graduates provided an additional 21.3% and Boston University, 16.0%. Table 2 also yields information on the years that these nine allopathic medical schools were founded [Harvard, the oldest, in 1782; and Brown

Table 1. Geographic Locations of Medical Schools Attended by Physicians Licensed in Rhode Island

Location	Women <1970*	Men <1970	Women >1970*	Men >1970	Total**
United States	40	724	816	1803	3383 [73.2]
Canada	5	30	28	37	100 [2.2]
Europe	22	175	34	135	366 [8.0]
Asia	39	96	52	114	301 [6.6]
Cent/South America	8	43	34	162	247 [5.4]
Middle East***	2	53	12	58	125 [2.7]
Africa	0	3	2	15	20 [0.4]
Australia	1	0	0	3	4 [0.1]
Not specified	1	8	3	20	32 [0.7]
Totals	118	1132	981	2347	4578

*: MD degree granted on or before 1970 = <1970 MD degree granted after 1970 = > 1970

**: Number and, in parenthesis, percentage.

***: Defined as medical schools situated in Egypt, Jordan, Syria, Lebanon, Iraq and Israel.

Table 2. New England Medical Schools Attended by Physicians Licensed in Rhode Island

Name of School	Year Founded	No. grads*	women <1970+	men <1970	women >1970	men >1970	total
Boston	1873	146	5	46	34	101	186
Brown	1973	63	0	0	130	196	326
Connecticut	1968	83	0	0	20	33	5
Dartmouth	1797	58	0	0	21	14	35
Harvard	1782	167	3	49	13	22	87
Massachusetts	1970	92	0	1	30	54	85
Tufts	1893	147	1	122	40	84	247
Vermont	1822	79	2	8	16	55	81
<u>Yale</u>	<u>1813</u>	<u>99</u>	<u>2</u>	<u>29</u>	<u>8</u>	<u>23</u>	<u>62</u>
Total		934	13	255	312	582	1162

*: Number of graduates in 1985.

+: MD degree granted on or before 1970 = <1970
MD degree granted after 1970 = >1970

the youngest, in 1973] as well as the average numbers of yearly graduates from these institutions.

Table 3 provides similar information on the Rhode Island-licensed graduates from the twelve New York State medical schools [679 physicians] and the fifteen medical schools situated in the remaining middle Atlantic states [604 physicians]. This geographic category includes New Jersey, Pennsylvania, Maryland and the District of Columbia. Delaware has no medical school within its borders.

The State University of New York, with four geographically discrete campuses [Brooklyn, Syracuse, Stony Brook, Buffalo] has educated 183 of Rhode Island's practitioners. New York University [representing the Bellevue and New York University Schools of Medicine amalgamated earlier in the 20th Century] trained 123 Rhode Island physicians.

Amongst the older middle-Atlantic state trained physicians [ie, those receiving the MD degree on or before 1970, numbering 332 physicians] only 4.8% were women. Amongst the 951 physicians receiving the MD degree after 1970, 22.5% were women.

The medical schools of Georgetown, Jefferson, Pennsylvania and New Jersey have educated large numbers of Rhode Island physicians. Collectively, these four schools account for 342 current medical practitioners in the state.

Table 4 summarizes the sites of professional education of the 100 Rhode Island physicians who obtained their MD degree from Canadian medical schools. Canada has 16 accredited schools of medicine stretching from Newfoundland

medical schools either in Quebec or Ontario provinces, but what is astonishing is the geographic diversity of this cadre of 100 physicians. There are Rhode Island physicians representing every one of the 16 Canadian medical schools but one [British Columbia.]

Many of the physicians licensed in 1895 by the state of Rhode Island had been educated in Canadian schools and had then migrated to Rhode Island to provide medical care for the many French-speaking workers who emigrated from the eastern Canadian provinces seeking jobs in the growing textile mills of 19th Century Rhode Island. Indeed, over a century ago, there were many communities within the state where the predominant language was French and where custom dictated that French-speaking physicians be recruited particularly from the smaller towns of Quebec Province.⁵

Table 5 summarizes the status of institutions offering medical education in the

Table 3. Middle Atlantic Medical Schools Attended By Physicians Licensed in Rhode Island*

Name of School	Year Founded	No. Grads#	Women <1970+	Men <1970+	Women >1971+	Men >1971+	Total
Albany	1955	128	1	14	9	33	57
Columbia	1767	157	2	26	12	47	87
Cornell	1898	121	0	17	15	33	65
Einstein	1955	183	0	2	19	24	45
Mt Sinai	1968	131	0	0	14	20	34
NY Med	1860	197	0	5	7	16	28
NYU	1842	171	1	47	20	55	123
Rochester	1925	91	1	13	12	31	57
State U NY**	**	567	3	36	43	101	183
<u>Total [NY State]</u>		<u>1746</u>	<u>8</u>	<u>160</u>	<u>151</u>	<u>360</u>	<u>679</u>
Georgetown	1851	201	1	38	15	67	121
George Wash.	1853	151	0	10	14	26	50
Hahnemann	1848	170	1	12	6	28	47
Johns Hopkins	1893	120	1	17	3	12	33
Howard	1868	118	0	2	0	3	5
Jefferson	1824	211	0	27	9	25	61
Maryland	1807	172	0	13	7	14	34
Med Coll Penn	1850	120	3	0	6	10	19
U Penn	1765	146	0	16	17	39	72
Penn St.	1967	97	0	0	0	11	11
Pittsburgh	1883	131	0	0	5	13	18
New Jersey***	***	184	0	13	18	57	88
Temple	1901	180	2	8	9	13	32
Uniformed Serv.	1976	121	0	0	2	11	13.
<u>Total [Mid-Atlantic, other]</u>		<u>2122</u>	<u>8</u>	<u>156</u>	<u>111</u>	<u>329</u>	<u>604</u>
Total [Mid-Atl.]		3868	16	316	262	689	1283

*: Middle Atlantic region jurisdictions with medical schools: New York, New Jersey, Pennsylvania, Maryland, District of Columbia.

#: Average number of graduates, per year, using data from 1985.

** : State University of New York has four medical campuses located in Syracuse [founded 1834], Buffalo [founded 1846], Brooklyn [founded 1860] and Stony Brook [founded 1962.]

***: College of Medicine & Dentistry of New Jersey has two medical campuses located at Newark [founded 1956] and Piscataway [founded 1966.]

Table 4. Canadian Medical Schools Attended By Physicians Licensed In Rhode Island

School	Year Founded	Avg. No. grad*	women <1970	men <1970	women >1970	men >1970	Total
Alberta	1913	113	0	1	1	3	5
British Columbia	1950	117	0	0	0	0	0
Calgary	1970	71	0	0	1	1	2
Dalhousie	1868	92	0	3	1	1	5
Laval	1853	152	0	3	0	1	4
Manitoba	1883	141	0	3	2	2	7
McGill	1832	205	3	8	12	16	39
McMaster	1969	94	0	0	4	1	5
Memorial [Newf.]	1969	48	0	0	1	0	1
Montreal	1878	197	1	2	1	0	4
Ottawa	1945	75	0	2	2	1	5
Queens	1854	80	0	1	1	2	4
Saskatchewan	1926	57	0	2	0	1	3
Sherbrooke	1966	90	0	0	1	1	2
Toronto	1887	236	0	2	1	6	9
West.Ontario	1878	105	1	3	0	1	5
Total			5	30	28	37	100

*: Average number of graduates per year in 1985. +: MD degree granted on or before 1970 = <1970
MD degree granted after 1970 = > 1970.

world of 1985. This particular year, 15 years prior to the year 2000, was chosen because the practicing physicians of Rhode Island had received their MD degrees, on average, 15 years prior to the year 2000.

Of the 159 nations of the world, in 1985, 115 maintained registered allopathic medical schools. The numbers of medical schools per nation varied from a low of one [typical of most African nations] to highs of 127 [United States], 114 [China], 106 [India], 87 [USSR], 80 [Japan], 76 [Brazil] and 57 [Mexico.]

A total of 1,338 WHO-registered world-wide medical schools graduated 166,895 physicians in 1985. The WHO, however, acts solely as a registering agency. It neither establishes standards, undertakes on-site inspections, nor even attempts to verify the information submitted by each member nation. Furthermore, some nations [eg, East Germany], in 1985, declined to submit any data on their medical schools contending that such data was confidential. In general, then, WHO reports are only modestly reliable but they represent the only global compilation of international schools of medicine and the sole source for numbers of physicians annually graduated by these institutions.

Table 6 lists the overseas locations of the medical schools which formally educated 1,158 physicians currently licensed to practice medicine in Rhode Island.

Seventy-two nations, on six continents, provided the education for these 1,158 practitioners. In Europe 25 of the

27 nations with established medical schools were involved in the medical education of Rhode Island's current roster of licensed physicians; the only exceptions were Denmark and Finland. Italy, however, dominated in having educated 131 of the 366 Rhode Island physicians educated in Europe. The majority of these Italian-trained physicians attended the University in Bologna.

Fourteen Asian nations, principally India, the Philippines and Pakistan, provided formal medical education for 301 Rhode Island physicians. The University of Santa Tomas, in Manila, provided more of these physicians, 37, than any other Asian school.

While there are 14 Middle East nations with established schools of medicine, only six [Egypt, Syria, Lebanon, Israel, Jordan and Iraq] provided education for 125 Rhode Island physicians. Egypt, more

than any other Middle East nation, provided formal medical education for Rhode Island doctors [44 physicians].

There are 239 recognized medical schools in the Caribbean region, Central and South America. Mexico has 57 schools, Brazil, 76 schools and Colombia, 21 schools. Most of the other nations of this region have but one national medical school. Of the 245 Rhode Island physicians with medical diplomas from Western Hemisphere nations south of the United States, over half were trained either in Mexico [87], the island of Dominica [33] or the island of Grenada [26].

COMMENT

There are, amongst the practitioners of Rhode Island, graduates of some of the most venerable and prestigious of international medical schools. These include schools of medicine in Padua [founded in 1361], Bologna [founded in the 14th Century], Montpellier [founded in 1180], Leyden [founded in 1575], and Edinburgh [founded in 1726].

The United States and Canada possess 143 medical schools; and graduates of 123 of these schools of medicine currently hold licenses to practice medicine in Rhode Island.

In terms of sites of formal medical education for their licensed physicians, the state of Rhode Island can boast of an astonishing measure of diversity. Allopathic physicians of Rhode Island can point to virtually every state in this country, almost every province in Canada and almost every nation of the world as their sites of formal preparation for the practice of medicine.

Table 5. Distribution of Medical Schools Recognized by World Health Organization

Region	No. Nations with medical schools	No. Med Schools	No. Graduates per year
Africa	23	53	2,321
Asia	22	482	63,439
Europe	27	354	59,984
Latin America*	26	239	16,178
Middle East**	12	53	8,022
Oceania ***	3	14	1,788
United States	1	127	13,290
Canada	1	16	1,873
Total	115	1,338	166,895

*: Includes nations of Caribbean region, Central and South America.

**: Includes Egypt, Jordan, Syria, Lebanon, Israel, Iraq, Libya, Tunisia, Algeria and Morocco.

***: Includes Australia, New Zealand and Fiji.

Table 6. Licensed Physicians of Rhode Island with Medical Degrees from Overseas Schools of Medicine

Continent	Women	Men
Europe	56 [27.1%]*	310 [35.1%]
Latin America**	41 [18.8%]	206 [23.2%]
Asia	89 [49.0%]	208 [23.6%]
Middle East***	14 [6.8%]	111 [12.6%]
Africa+	2 [1.0%]	18 [2.0%]
Australia, New Zealand, Fiji	1 [0.5%]	3 [0.2%]
Not specified	4 [1.9%]	28 [3.2%]
Total	207	884

*: Number and, in brackets, percentage

** Includes nations of Caribbean region, Central and South America.

***: Defined as Egypt, Jordan, Syria, Lebanon, Israel, Iraq, Libya, Tunisia, Algeria and Morocco. +: Nations of subSaharan Africa

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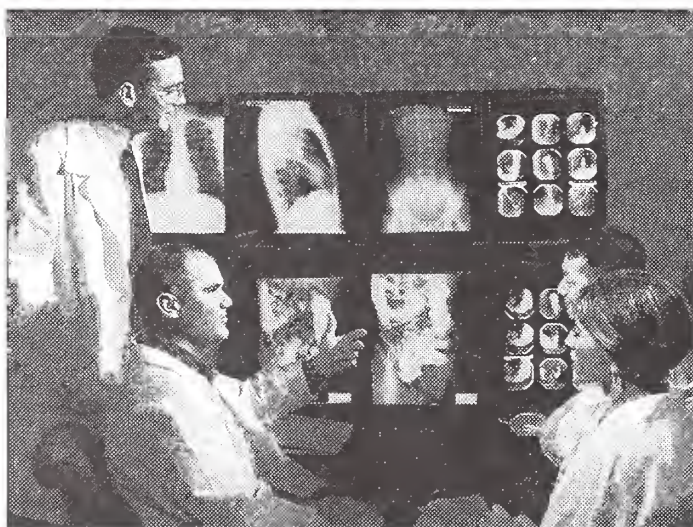
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The Emergence of Bioterrorism as a Public Health Concern in the 21st Century: Epidemiology and Surveillance

(First in a series of articles)

Thomas Bertrand, MPH, Utpala Bandy, MD, MPH, Gregory T. Banner, MS, and Walter S. Combs, Jr., PhD

BACKGROUND

Unbeknownst to Sir Jeffrey Amherst in 1763, he essentially was initiating the first documented "bioterrorist" acts in the Western Hemisphere. In an effort to fight Native American tribes for land in New England, Sir Jeffrey Amherst, commander of British forces in North America, wrote his colonel: "Could it not be contrived to send smallpox among these disaffected tribes of Indians? We must on this occasion use every stratagem in our power to reduce them." The colonel replied: "I will try to inoculate them with some blankets that may fall in their hands, and take care not to get the disease myself."¹

Amherst had never heard of viruses, immunity or vaccination. In fact, a century would pass before scientists accepted the idea that microbes could cause disease. Amherst did know that Native Americans were especially vulnerable to the sickening and disfiguring power of smallpox, and that he could intentionally infect them with it. His strategy, to strike in a covert manner without using guns or leaving a trace, is likely to be employed by terrorists today who may use biologic and chemical agents.

A NATIONAL AND INTERNATIONAL PERSPECTIVE ON BIOTERRORISM

Fortunately, Rhode Island has not been a target of a biologic or chemical terrorist activity, with the exception of hoaxes. From January 1998 to June 2000, two bioterrorist threats have been received by local organizations in Rhode Island. Upon State and Federal investigation, these threats have been unsubstantiated claims of envelopes containing anthrax, with no subsequent harm or loss of life; the only impact was minor disruptions to the normal course of business operations. However, the City of Providence remains on Congress's Nunn-Lugar-Domenici list of one hundred and twenty possible targets of bioterrorist activity. This list was created in response to growing concern about

the United States' vulnerability to a potential deliberate and deadly attack using chemical, biological, or nuclear agents - known as weapons of mass destruction (WMDs).

Heightened concern regarding WMDs occurred after a terrorist incident that took place in Tokyo in 1995, when members of the Aum Shinrikyo cult placed open containers of sarin nerve gas on subway cars. The incident killed twelve, wounded sixty, and sent 5,500 victims to hospitals. This religious cult also developed a biological weapons arsenal and attempted to aerosolize anthrax and botulism spores in downtown Tokyo.

International investigations also revealed an extensive biological weapons capability of the Iraqi government and the discovery of an extensive bioweapons program prior to the breakup of the Soviet Union.

Recent United States experiences with terrorists include: the World Trade Center bombing, the Oklahoma Federal Building bombing, and the U.S. embassy bombings in Africa. The ability of terrorist groups to use biological weapons to achieve their goals is enhanced by the low cost and low technology necessary to produce large volumes of agents and the ability to convert readily available commercial equipment for agent dissemination.

Because of these concerns, Congress passed three major laws aimed at preventing the use of biological weapons and reacting to any incident. Those statutes are The Biological Weapons Act of 1989, the Chemical and Biological Control and Warfare Elimination Act of 1991, and the Anti-Terrorism and Effective Death Penalty Act of 1996. In the Anti-Terrorism Act of 1996, Congress specified that the Centers for Disease Control and Prevention (CDC) create and maintain a list of biological agents with the "potential to pose a severe threat to public health and safety."

CDC developed regulations govern-

Abbreviations Used:

BT	bioterrorism
CDC	Centers for Disease Control and Prevention
HEALTH	Rhode Island Department of Health
WMD	weapon of mass destruction

ing biological agents to accomplish four goals: 1) the identification of biological agents that are potentially hazardous to the public health; 2) monitoring procedures for acquiring and transferring of the restricted agents; 3) safeguards for the transportation of agents; and 4) a system to alert law enforcement agents when an attempt is made to acquire a restricted agent. CDC has placed twenty-four infectious agents and twelve toxins on the restricted list (Table 1).

The listed agents are those considered to have the potential to be biological weapons. The diseases they cause can either incapacitate or kill. Importantly, the restricted agents are not the only agents that can be used for bioterrorism. A 1984 *Salmonella* outbreak in The Dalles, Oregon, was linked to a religious cult that wanted to influence the outcome of an election. Salad bars at ten restaurants were contaminated with *Salmonella typhimurium* on different occasions. In a county that usually had five cases of *Salmonella* a year, 751 cases were documented. The public health surveillance system identified the outbreak, and the source of the outbreak was discovered during an FBI investigation of the cult for other criminal activity. During this investigation, the FBI staff discovered a biological laboratory and a vial containing *Salmonella* of the same strain as that identified in the outbreak.

The increasing awareness of the United States' vulnerability to a bioterrorist incident, coupled with the growing unease about the simplicity of making and using biological and chemical weapons, has prompted Congress to

Table 1. List of Restricted Agents

Viruses*

Crimean-Congo hemorrhagic Fever
Eastern equine encephalitis
Ebola
Equine morbilliviruses
Lassa Fever
Marburg
Rift Valley fever
South American hemorrhagic fever
(Junin, Machupo, Sabia, Flexal,
Guanarito)
Tick-borne encephalitis complex
Variola major (smallpox)
Venezuelan equine encephalitis
Viruses causing hantavirus pulmonary syndrome

Toxins**

Abrin
Aflatoxins
Botulinum toxins
Clostridium perfringens epsilon toxin
Conotoxins
Diacetoxyscirpenol
Ricin
Saxitoxin
Shigatoxin
Staphylococcal enterotoxins
Tetrodotoxin
T-2 toxin

Bacteria*

Bacillus anthracis
Brucella abortus, melitensis, suis
Burkholderi mallei
Burkholderi pseudomallei
Clostridium botulinum
Francisella tularensis
Yersinia pestis

Fungi

Coccidioides immitis

Rickettsiae
Coxiella burnetii
Rickettsia prowazekii
Rickettsia rickettsii

*Exemptions for vaccine strains provided

** Exemptions for toxins for medical use, inactivated for use in vaccine, or toxin preparation for biomedical research

make funding and domestic preparedness a priority. As a result, the Rhode Island Department of Health has received funding for the following bioterrorism focus areas: Epidemiology and Surveillance, Laboratory, and the Health Alert Network.

The grant program will also enable HEALTH to enhance infrastructure in several important areas, including the capacity to address emerging infections and to respond to health-related emergencies. In addition to the enhancement of the surveillance and epidemiology functions described here, the grant provides funds to develop capacity for laboratory testing for organisms that may be used by terrorists. Further, HEALTH is working with the Hospital Association of Rhode Island and the cities and towns to build capacity to respond to terrorist events. A key component of this effort is creation of a system for secure electronic communication among HEALTH and its partners.

BIOTERRORISM PLANNING EFFORTS IN RHODE ISLAND: EPIDEMIOLOGY AND SURVEILLANCE

Bioterrorism attacks may be announced, as in the anthrax hoaxes recently experienced in Rhode Island, or more likely

may be covert as in The Dalles, Oregon, case. The agents listed as most likely to be used as weapons are smallpox, anthrax, and plague. The first evidence of their use will most likely be cases that present in hospital emergency rooms. Most health care providers have not seen a case of smallpox, anthrax, or plague, and early diagnosis and reporting is essential not only for the case, but also to initiate preventive and therapeutic measures for other exposed individuals.

Overall, the role of surveillance and epidemiology in the event of a bioterrorist incident is critical in the rapid detection of the attack. Performing analysis to assess the public health threat and providing assistance in the coordination of health care services during a crisis will be key. The Division of Disease Control and Prevention, Office of Communicable Disease, is taking the lead in both improving HEALTH's internal capacity to perform these functions, and working with external partners (i.e., physicians, hospitals, and laboratories) to ensure that Rhode Island reaches a high level of bioterrorism readiness.

The first step towards bioterrorism preparedness is the streamlining of disease reporting processes so that if a covert

bioterrorist attack occurs, it is quickly detected and reported to HEALTH. The 24-hour HEALTH on-call system (phone number - 272-5952) has been updated to respond to reports of a suspected bioterrorist event. Disease reporting guidelines have been revised to include specific BT agents, as follows: "Exotic diseases (smallpox, plague, etc.) and unusual group expressions of illness (communicable or otherwise) which may be of public health concern should be reported immediately." (Revised reporting instructions, the "blue card," have been included as an attachment in the center of this publication.) Medical guidelines for identifying and treating infections with suspected bioterrorist agents will be sent to all hospital emergency rooms, intensive care units, and infectious disease physicians. Site visits will be scheduled with hospital laboratories to give in-service agent-specific trainings related to bioterrorism. A laboratory manual addressing specimen handling and reporting protocols has been written and will be distributed.

HEALTH has prepared an internal protocol for responding to a suspected bioterrorist event. This protocol delineates the roles of the medical directors, public health nurses, epidemiologists, and other support staff. Methods of contacting HEALTH staff and national experts have been documented through contact lists. Plans are in place to develop bioterrorism agent-specific case questionnaires, electronic database analysis, and public education messages.

The role of hospitals will be critical in the effective response to a bioterrorism incident. A contract has been established with the Hospital Association of Rhode Island to conduct a comprehensive assessment of hospital bioterrorism readiness. In coordination with the Health Alert Network efforts, this assessment will focus on emergency rooms' and intensive care units' ability to promptly report suspected cases/clusters of disease, technological capacity to report diseases, utility of hospital disaster plans, and gaps in hospital communication systems. A plan will be prepared to improve all aspects of hospital BT surveillance and reporting capabilities.

Following a bioterrorism incident, critical decisions will have to be made related to recommended treatment guidelines, obtaining antibiotics and vaccines,

prioritizing populations for treatment, and isolation or quarantine procedures. As part of an incident command team, epidemiology and surveillance staff from HEALTH will provide expertise on these topics and assist in the implementation of a crisis response plan.

CONCLUSION

While some believe an actual attack with biological weapons is imminent, others believe the possibility of a bioterrorist act remains relatively low. "The likelihood is entirely unknown," said Donna Shalala, Secretary of Health and Human Services. "It may never occur. But we've seen terrorism emerge as one of the problems of the post-Cold War world. We must not be afraid, but we must be aware."²

FOR MORE INFORMATION

A detailed report of the "National Symposium on Medical and Public Health Response to Bioterrorism" is posted on the Johns Hopkins University web site: "<http://www.hopkins-biodefense.org/>"

Visit the CDC's website on bioterrorism at <http://www.bt.cdc.gov>.

COMMENTS

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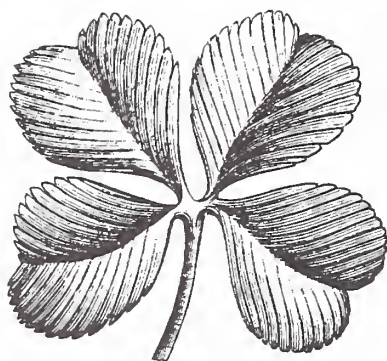
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Medical Myths

Ignorance is preferable to error; and he is less removed from the truth who believes nothing, than he who believes what is wrong. — THOMAS JEFFERSON, Notes on the State of Virginia



B12 Supplementation: Must be Parenteral

Philip O'Dowd, MD

Defined as a low or low normal serum B12 level with elevated methylmalonic acid (MMA) and homocysteine (HC) levels, the incidence of significant B12 deficiency in some geriatric populations has been reported as high as 15%.¹ This high rate has been attributed, in part, to senile gastric atrophy with achlorhydria allowing bacterial overgrowth and competition for the dietary B12. Hematologic abnormalities are uncommon in this population but some neuropsychiatric abnormalities have been reported to improve with supplementation.¹ Age-independent conditions associated with clinically significant B12 deficiency, most with megaloblastic hematopoiesis, include pernicious anemia, post-gastrectomy syndrome, other bacterial overgrowth syndromes, ileal disease or surgery, fish tapeworm infection, strict vegetarianism, and various uncommon hereditary disorders of B12 transport proteins, intrinsic factor (IF) or the IF/B12 receptors. Recently proton pump inhibitors have been demonstrated to reduce absorption of dietary B12 raising the question of whether prolonged therapy with these agents may lead to deficiency.^{2,3}

The usual Western diet contains about 6 microgm/d of B12, of which only 1 microgm/d is absorbed. These are small quantities. Typical daily iron intake and absorption, for example, are three orders of magnitude greater, at the milligram/d level.

Efficient, facilitated absorption of the scant dietary B12 is mediated through the R protein/intrinsic factor/ileal receptor pathway emphasized in medical school courses and most textbooks. At the low dietary levels of B12 this is the principal route for absorption. It is not the sole route, however. If pharmacologic doses of B12 are given orally, absorption occurs throughout the upper bowel apparently by mass-action principles. Such daily high dose oral therapy (range: 300 microgm/d-2 mg/d po) has been demonstrated to be therapeutically and biochemically equivalent to monthly parenteral (injection) therapy.⁴ Clinical studies have even demonstrated the efficacy of the sublingual and intranasal administration.^{5,6} There are no demonstrated

clinical toxicities of high dose oral B12 therapy (even at a megadose of 60 mg/d).⁷ The cost of the vitamin by either route

is relatively inconsequential,⁸ but the elimination of the need for needles or monthly visits by medical personnel may be a substantial economic or psychological advantage. Since absorption occurs throughout the gut independent of the presence of Intrinsic Factor, high dose oral therapy is effective even in pernicious anemia, after gastrectomy or with ileal disease. In short bowel syndrome or diffuse structural malabsorption states such as sprue the oral route may be ineffective. B12 tablets of sufficient dose (300-2000 microgm/d) must be prescribed. The amount of B12 in a typical multivitamin tablet (<20 microgm per tablet), although greater than the usual dietary load, is insufficient for adequate mass-action absorption.

Although studies demonstrating the efficacy of oral therapy have been in the literature for decades,⁹ and despite recent confirmatory studies,² surveys have demonstrated that the majority of practicing physicians remain unaware of the option of oral B12 therapy even though they would welcome such an addition to the therapeutic armamentarium.¹⁰

In a reliable patient capable of monthly self-injection either route is an option. In patients who require monthly visits by health care personnel for administration, or in circumstances in which needles and syringes might be misused or abused, the oral route may be preferred. Routine laboratory confirmation of the efficacy of the oral route should not be necessary, the above studies having demonstrated such. Normalization of serum MMA and HC levels would provide such confirmation in unusual cases. Concomitant folate deficiency should, of course, be considered and treated in many of the above conditions.

Abbreviations Used:

HC	homocysteine
IF	intrinsic factor
MMA	methylmalonic acid

*... the majority of
practicing physicians
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therapy even though they
would welcome such an
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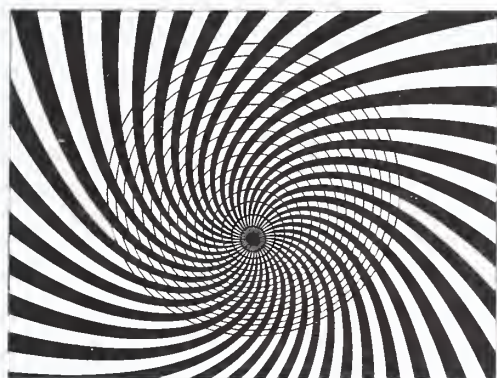
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IMAGES IN MEDICINE

A Case Of Pulmonary Embolism Diagnosed by CT Scan: Yet Another Use for a Familiar Imaging Modality

Peter Giuliano, MD, and John J. Cronan, MD

Abbreviations Used:

CT computed tomography
VQ ventilation perfusion

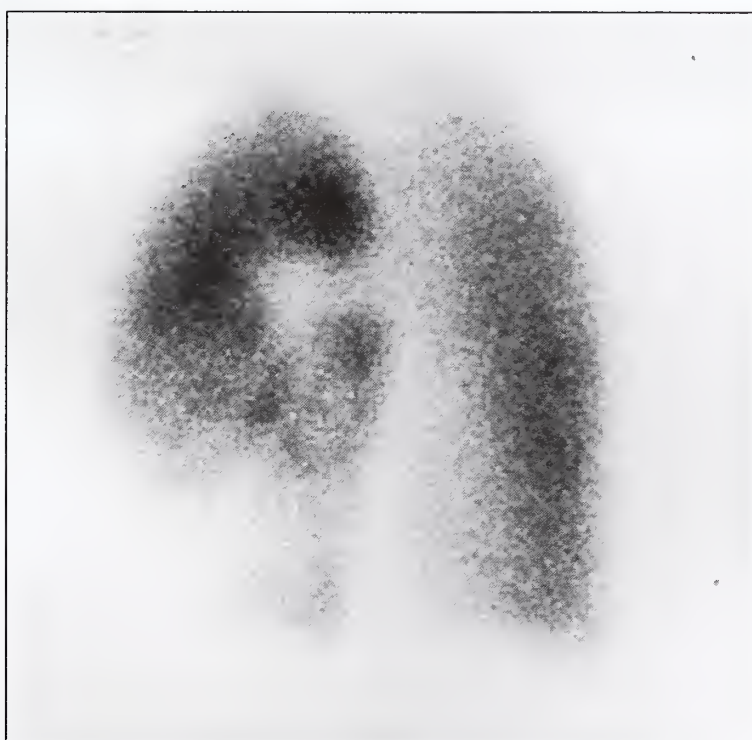


Figure A: Lung Perfusion Scan demonstrating defects in apicoposterior segment of left upper lung which was mismatched on subsequent ventilation, and matched in the left lower lobe.

HISTORY

An 81 year-old male presented with complaints of shortness of breath and chest pain. Rule out pulmonary embolus.

IMAGING FINDINGS

VQ Scan: mismatched defect in the apicoposterior segment of the left upper lobe giving an intermediate probability scan.

CT pulmonary angiography. Large thrombus in the left pulmonary artery extending superiorly and caudally.

DISCUSSION

Spiral CT pulmonary angiography was introduced in the early 1990s and has been steadily gaining acceptance for imaging pulmonary embolisms.¹ A sensitivity of 92% with a specificity of 96% has been quoted in a large study in the recent literature² with a negative predictive value of 99%.³ Additionally it has been found to have a high degree of inter-observer agreement⁴ and provided additional, relevant information 54% of the time.³

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Figure B: Transaxial CT image demonstrating close (small arrows) in the left pulmonary artery.

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John J. Cronan, MD, is Professor and Chairman, Department of Diagnostic Imaging, Brown University School of Medicine, and Radiologist-in-Chief, Rhode Island Hospital.

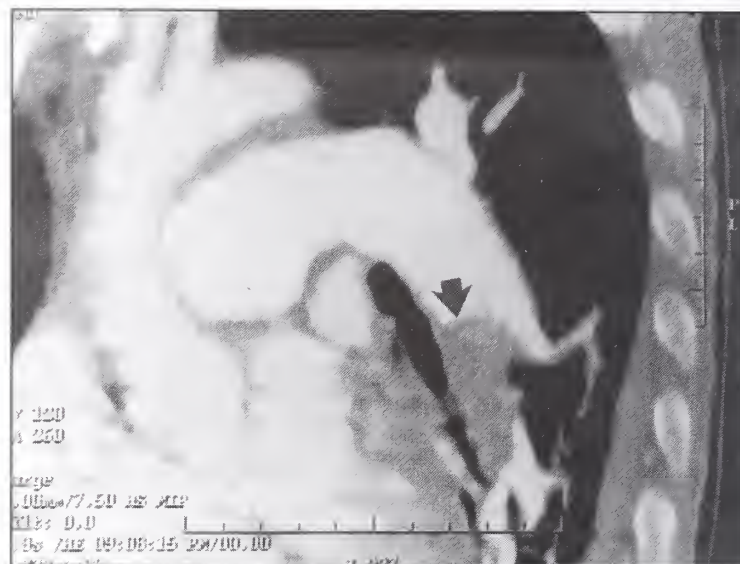


Figure C: Parasagittal reconstruction CT image showing clot (large arrow) in left pulmonary artery.

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Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report

Provisional Occurrence Data
from the
Division of Vital Records

Underlying Cause of Death	Reporting Period			
	August 1999	12 Months Ending with August 1999		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	221	3,043	307.8	3,855.0
Malignant Neoplasms	228	2,514	254.3	7,004.0
Cerebrovascular Diseases	43	549	55.5	676.0
Injuries (Accident/Suicide/Homicide)	40	369	37.3	6,587.0
COPD	37	508	51.4	397.5

Vital Events	Reporting Period		
	February 2000	12 Months Ending with February 2000	
	Number	Number	Rates
Live Births	1,067	13,217	13.4*
Deaths	887	10,016	10.1*
Infant Deaths	(6)	(97)	7.3#
Neonatal deaths	(5)	(80)	6.1#
Marriages	349	7,788	7.9*
Divorces	323	2,801	2.8*
Induced Terminations	500	5,016	379.5#
Spontaneous Fetal Deaths	92	1,075	81.3#
Under 20 weeks gestation	(83)	(1,005)	76.0#
20+ weeks gestation	(9)	(70)	5.3#

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 988,480

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population

Rates per 1,000 live births



Controversies in Adult Immunization

Raymond Maxim, MD

Despite an enormous national effort from both public and private agencies, adult immunization remains a significant quality issue. The evidence surrounding the immunization issue is compelling but there is still a large gap between the evidence and everyday practice. The medical community has not been successful in creating the same sense of urgency for adult immunization as we have for childhood immunizations. Immunization rates in Rhode Island, and nationally, demonstrate that more than one third of adults at risk do not receive the proper immunizations. This occurs despite mass immunization clinics, intensive public education campaigns and a concerted effort to encourage physicians and other practitioners to immunize their patients.

The disparity has stimulated efforts to find ways to increase utilization outside of the traditional office setting or immunization clinic. Many creative ideas for providing access to immunizations have been tried throughout the country. These include immunizing people at polling places, churches, and even drive-through clinics. The hospital remains an appropriate site to find patients who are most at risk. Most patients hospitalized for pneumococcal pneumonia or influenza were hospitalized for some other reason in the preceding 3-5 years.¹ This, combined with the 20,000 - 40,000 vaccine-preventable deaths each year,² makes a strong case for screening and immunizing patients while they are in the hospital. Rhode Island's hospitals have not yet implemented inpatient screening and immunization programs. As a result Rhode Island ranks among the lowest in the nation with an inpatient screening/immunization rate of 6.8% for pneumococcal vaccine and 9.6% for influenza. Rhode Island is not alone - most of the nation is doing poorly with inpatient immunizations. Local hospitals have recognized this as an area that needs attention and are working as a team to create a common statewide approach.

Some hospitals have taken this to heart and have developed standing order programs that are very successful. Using standing orders, six Minnesota hospitals achieved a rate of 40%.³ Other hospitals have had similar successes. A review of the problems encountered by these hospitals during the development of their programs shows that other than the logistics of setting up a program, the only barrier

Abbreviations Used:

HCFA	Health Care Financing Administration
INR	international normalized ratio
KWISP	Kerr L. White Institute Stroke Prevention Project
PRO	Peer Review Organization
RIQP	Rhode Island Quality Partners
TIA	transient ischemic attack

was the physician's reluctance to participate, because they believe that immunizations are an outpatient problem. Unfortunately, outpatient immunization programs have not been able to reach over 1/3 of those who should be immunized. A patient's hospital encounter (inpatient or emergency department) may be a missed opportunity for reaching the individuals. Many patients see their physician only once a year and not always at optimal times for immunization. Nonfebrile illnesses in hospitalized patient should not prevent immunization if the patient is stable. Nor should febrile illnesses prevent immunization when the cause of fever is known and is treated. If there are concerns about immunizing a patient in the hospital, home care can arrange for vaccination after discharge.

Repeat pneumococcal vaccination has been a major concern of many practitioners. Unfortunately, elderly patients often do not remember the last time they received a pneumococcal vaccination. It can be difficult to determine

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the immunization status of an elderly patient in an office setting when records have been transferred or a patient is new to the community. It is even more difficult at mass immunization clinics. Few older patients keep their own immunization records. This has rightfully raised the question regarding repeat vaccination. In the pediatric community it is a fairly common practice to reimmunize a child if the vaccine status is in doubt. Adult medicine and mass immunizers have yet to embrace this concept for fear of an increase in adverse reactions.

The evidence suggests the concern about serious adverse reactions is unwarranted. A 1999 comparative interventional study conducted by Jackson et al of 1414 patients between 50 and 74 years old demonstrated no severe reactions.⁴ All reactions were localized Arthus-type. The incidence of local reactions increased after reimmunization from a baseline of 3% to 11%. None of these reactions were severe and most resolved within three days. The incidence was even less (8%) in those patients with chronic diseases such as diabetes mellitus, cardiovascular disease, pulmonary disease or cirrhosis. These are the patients we are most interested in protecting from pneumococcal disease. In addition, a prospective cohort analysis and case study reported by Snow et al of 69,974 Medicare beneficiaries demonstrated no increase in hospitalizations in those patients receiving a second vaccination.⁵ The administrative records of 5% of Medicare part B claims between 1985 and 1988 were randomly sampled for pneumococcal vaccine administration (CPT codes 90732 and J6065). Of the 1099 patients with a second vaccination only 39 were admitted to the hospital within thirty days of the revaccination. None of the admissions were vaccine-related according to a review of ICD-9-CM codes and discharge diagnoses. There is no evidence base to prevent repeat immunization of pneumococcal vaccine in patients where status is unknown. The possibility of hospitalization or death from pneumonia or invasive pneumococcal disease outweighs the risk of potential localized reactions.

In summary, neither hospitalization nor possibility of reaction to a repeat vaccination should prevent us from providing these much-needed vaccines. We ask you to consider your approach to immunization in light of the evidence presented above. As always, please contact us concerning this article or other health care quality issues.

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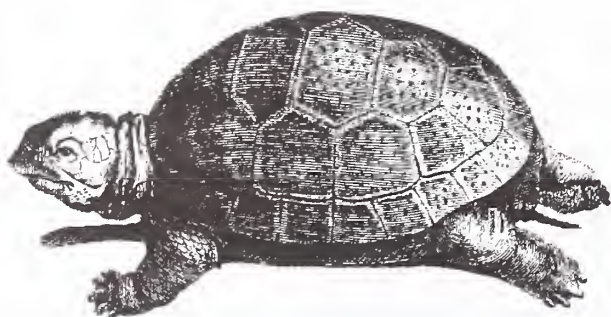
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Health Disparities Among Racial and Ethnic Groups in Rhode Island

Jay S. Buechner, PhD

The health of racial and ethnic minority populations has been a focus of public health for many years, due to the disparities in health status, exposure to health risks, and access to health care that are revealed when these populations are compared to the white, non-Hispanic population. At the national level, the impact of poor health on the quality and length of life for minority citizens was considered to be so fundamental that one of the three overarching goals of *Healthy People 2000* was to reduce health disparities among the disadvantaged.¹ In *Healthy People 2010*, the goal has been made even more challenging; the nation is now committed to the elimination of such disparities entirely.²

Early in the last decade, the health disparities of minority populations in Rhode Island were documented in conjunction with the establishment of a minority health program in the Rhode Island Department of Health.^{3,4} Many of the measures used were those that had been selected to monitor progress toward the achievement of the statewide health objectives in *Healthy Rhode Islanders 2000*.⁵ Recently, as the Department has been evaluating the state's level of success in achieving those objectives, we have also re-measured the extent of health disparities in our minority populations. This report presents the

findings for three selected measures of health status for which minority populations have been historically disadvantaged: homicide rates, infant mortality rates, and lead poisoning rates.

Methods

Measures were defined as in *Healthy Rhode Islanders 2000*.⁵ Age-adjusted homicide rates by race and ethnicity for Rhode Island residents were computed from the number of deaths with an underlying cause of death of homicide for the period 1995-1997 and Rhode Island population estimates by age, race, and Hispanic origin for 1995-1997,⁶ using the 1940 United States population as standard. Infant mortality rates were computed as deaths prior to one year of age divided by total live births during the period 1995-1997. Rates of lead exposure for children ages 6 years and younger were computed as the number of children with blood lead levels of 15 micrograms per deciliter divided by the number of children tested during 1998. For each measure, rates were computed for persons of each race and for persons of Hispanic origin (independent of race where possible).

Results

There were marked differences in homicide rates by race and Hispanic origin in Rhode Island during 1995-1997. Rates for Blacks, Native Americans, and Hispanics were higher than the statewide rate; rates for Asians and non-Hispanic Whites were lower. (Figure 1) The rate for Black Rhode Islanders was especially elevated, eight times as high as the statewide rate. Since the period 1989-91, the statewide homicide rate declined 33% in Rhode Island, but the decline for Black Rhode Islanders was only 7%. Declines for Asians (83%) and Native Americans (71%) were relatively large, and the decline for Hispanics (34%) was close to the state average.

Infant mortality rates for minority racial and ethnic groups have historically been

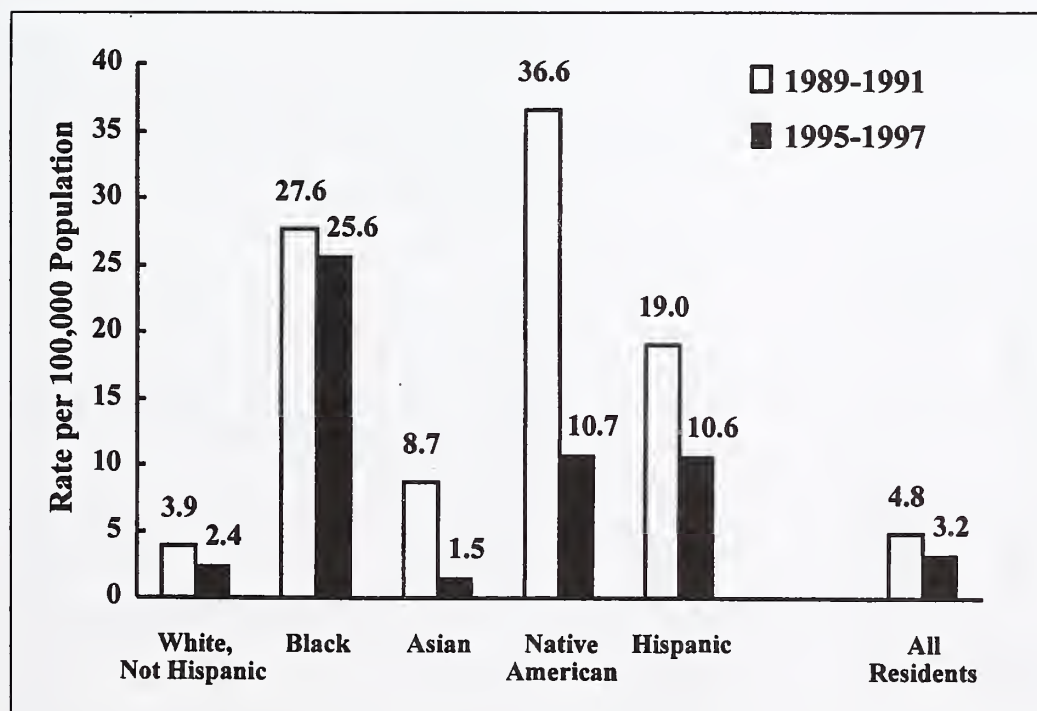


Figure 1. Average Annual Homicide Rate (Age-Adjusted), by Race and Ethnicity, Rhode Island, 1989-1991 and 1995-1997.

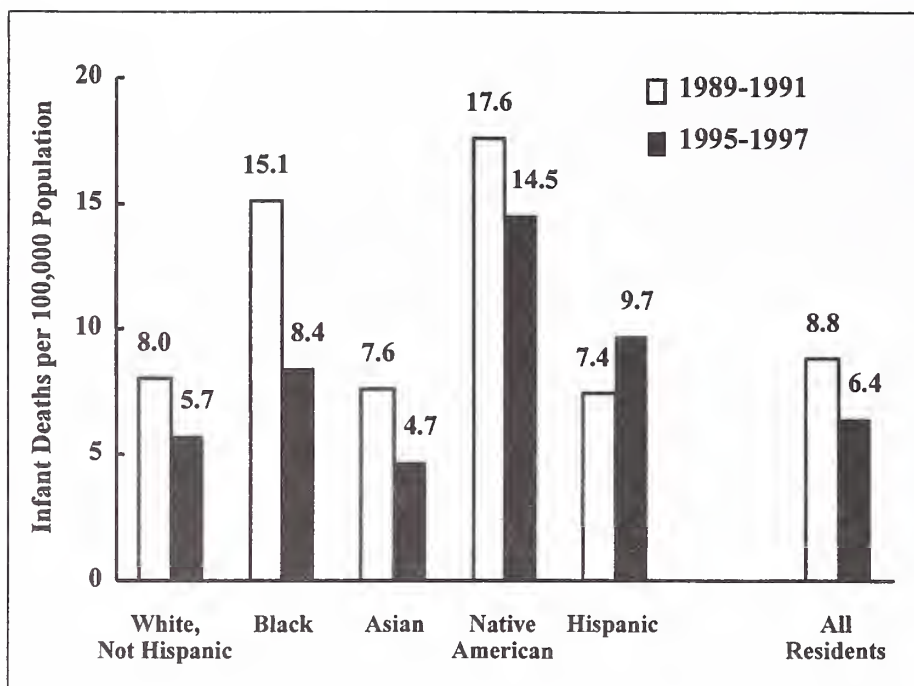


Figure 2. Average Annual Infant Mortality Rate, by Race and Ethnicity, Rhode Island, 1989-1991 and 1995-1997.

elevated both in Rhode Island and nationally. During 1995-1997, rates in Rhode Island for Blacks, Native Americans, and Hispanics ranged between 31% and 127% higher than the statewide rate, while the rate for Asians was 27% below the state average. (Figure 2) Since 1989-91, infant mortality rates for Blacks (down 44%), Asians (down 38%), and Native Americans (down 18%) have fallen, more rapidly than the statewide rate (down 27%) for Blacks and Asians, but the rate for Hispanics has increased 31%.

Rates of elevated blood lead levels were higher for children in all minority populations during 1995-97, with the rate for Asian children nearly six times the statewide rate. (Figure 3) Compared to 1994 rates (the first year for which data by race and ethnicity are available), only the rate for Hispanics has decreased more rapidly (down 68%) than the statewide rate (down 65%). Rates for Black and Native American children (down 49% and 22% respectively) have decreased less

rapidly than average, and the rate for Asian children has increased 44%.

Discussion

Homicide rates, infant mortality rates, and rates of elevated blood lead levels are all indicators of health conditions affecting the children and young adults in a population. Moreover, they reflect adverse factors that impact health more broadly, such as poor access to prenatal care, high rates of non-fatal violence, and poor housing conditions. These conditions and associated factors are among those that determine the lifelong health status and overall quality of life of a community's members. It is an accomplishment of some note that the statewide rates for these conditions have fallen by between 27% and 65% in a period of less than a decade in our state. These improvements represent good progress toward the objectives of *Healthy Rhode Islanders 2000*.

However, the progress has not been uniform across all racial and ethnic groups. For each of the three indicators examined, there is at least one racial and ethnic minority population that has seen its rate increase substantially relative to the statewide rate, thus increasing the disparity for this condition in this group. Thus, the progress in reducing disparities in these critical health indicators over the past decade in Rhode Island has been mixed despite the excellent improvements statewide. Put in this context, the *Healthy People 2010* goal of eliminating health disparities must be viewed as a formidable challenge for our state's public health community.

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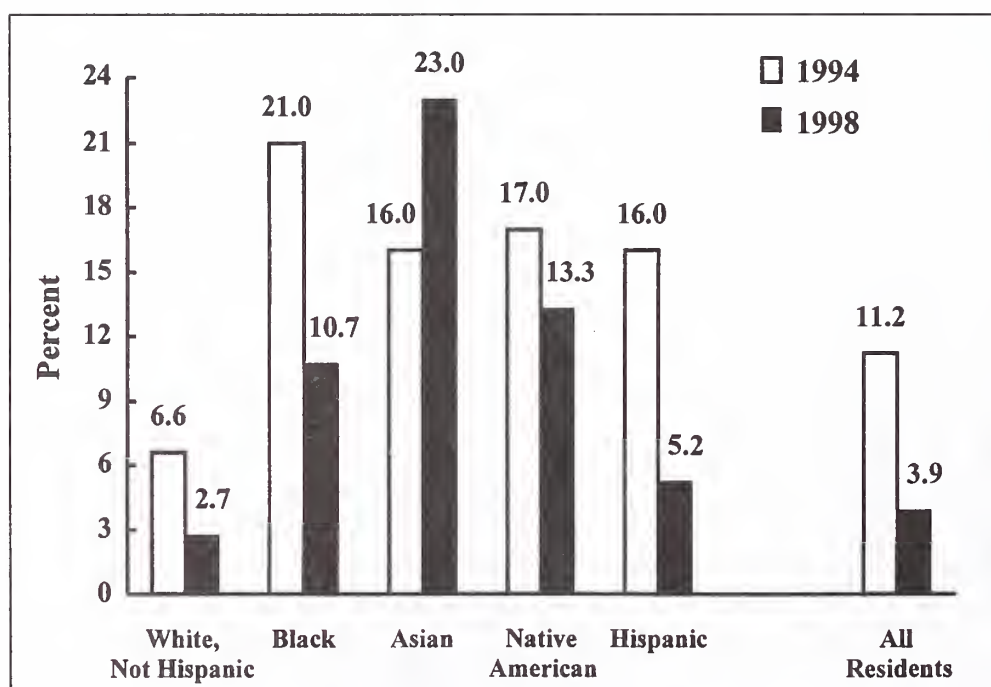


Figure 3. Prevalence of Blood Lead at 15 micrograms/dL or Greater, Ages 0-6 Years, Rhode Island, 1994 and 1998.

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Recommending High-Fiber Diets to Prevent Colorectal Cancer

Nancy A. Sutton, MS, RD

THE ISSUE

In 1971, Burkitt hypothesized that the high-fiber diet of West African natives was responsible for their low levels of colorectal cancer.¹ Since then, dietary fiber was identified as a modifiable risk factor for the prevention of colon and rectal cancers; evidence supporting this theory grew; and Americans were advised to eat plenty of fruits, vegetables, and whole grains to prevent colorectal cancer.

A few recent studies, however, have challenged the protective effect of dietary fiber on colorectal cancer, and they have received the attention of the media. In January 1999, the *New England Journal of Medicine* (NEJM) published results of the Nurse's Health Study, which found no link between high-fiber diets and colon cancer,² and this past spring, the media highlighted two studies published in the NEJM with similar findings.^{3,4}

National recommendations come into question under such circumstances, not only by the public, but also by the health professionals who use them. It is not the first time. The American people have become tired of contradictions between dietary recommendations to prevent chronic diseases and the headline news. The medical community is split on the issue of sodium and high blood pressure. There are mixed messages on the consumption of alcohol, dietary cholesterol, and total dietary fat and fatty acids and the development of heart disease. Now the question arises: "Should we recommend a high-fiber diet?"

THE FINDINGS

In January 1999, *NEJM* published results from the Nurse's Health Study. In this large, well-designed study, Fuchs et al. looked at the relation between amounts of total dietary fiber, cereal fiber, fruit fiber, and vegetable fiber consumed by approximately 88,000 women over a 16-year period, and their experience with colorectal cancer and adenomas. No link was found between the intake of total dietary fiber or cereal and fruit fibers and colorectal cancer or adenomas. Surprisingly, they found a positive association

Abbreviations Used:

ACS	American Cancer Society
AICR	American Institute for Cancer Research
NEJM	New England Journal of Medicine

between higher intakes of vegetables and the development of colorectal cancer.²

Two current articles, published in the April 21, 2000 issue of *NEJM*, were also publicized in the media. One reported the results of a study that tested the effect of a low-fat, high-fiber diet on the recurrence of colorectal adenomas during a four-year period.³ The other looked at the effects of a high-fiber supplement on the recurrence of colorectal adenomas during a three-year period.⁴ The findings of both studies indicated that increasing fiber in the diet did not prevent the recurrence of colorectal adenomas.^{3,4}

These three studies are actually just a few of many that have

Table 1: Other possible risk factors for the development of colorectal cancer.^{5,7,8}

Risk factor	Comments
Physical inactivity	Moderate physical activity several days a week appears to protect against colorectal cancer. Physical activity can help prevent obesity.
Red meat	Red meats include beef, pork, and lamb. Diets high in red meats may increase colorectal cancer.
Dietary fat	Saturated or animal fat may be associated with colorectal cancer. There is question of whether it is the fatty acids or something else in red meats that is the cause. High fat diets tend to increase the risk of obesity.
Folic Acid	Research indicates that folic acid supplements may be more beneficial than a diet with high levels of folate.
Obesity	Obesity may increase colorectal cancer. Overweight is defined as a body mass index (BMI) between 25 and 30. Obesity is defined as a BMI above 30.
Alcohol	Alcohol may be linked to the development of colorectal cancer. Alcohol refers to wine, beer, and other types of alcoholic beverages.
Tobacco	Cigarette smoking may be linked to the development of colorectal cancer.

Table 2: Goals for Nutrition in the Year 2000⁹

Avoid overweight and weight gain during adulthood.
Be moderately to vigorously active for at least 30 minutes on most days.
Consume five servings of fruits and vegetables daily.
Replace red meat with chicken, fish, nuts, and legumes, and consume dairy products at most in moderation.
Limit alcohol consumption to one drink a day for women and two for men.
Consider taking a multivitamin containing folic acid, particularly if alcohol is consumed daily.
Consume cereal products in a minimally refined, whole grain form.

found a weak or no association between dietary fiber and the development of colorectal cancer. However, the jury is still out. In the Nurse's Health Study, were the amounts of dietary fiber in the subjects who reported eating high-fiber diets (with an average of 26 grams per day) enough to make a difference? How does this amount of fiber compare to the levels consumed by the natives of West Africa that Burkitt observed? Are 16 years long enough to measure an effect on the development of cancer? Are three or four years enough time to see an effect? Do fiber supplements simulate whole food sources of fiber? What about the other components of fruits, vegetables, and whole grains beside the insoluble and soluble fibers? What role is played by the vitamins, minerals, antioxidants, and phytochemicals, such as isoflavones, isothiocyanates, indoles, or allyl sulfides, in protecting the body from certain cancers?

Reports based on a thorough review of the literature by such agencies as the American Cancer Society (ACS) and the American Institute for Cancer Research (AICR) were published in the late 1990s. The AICR's 1997 report, *Food, Nutrition and the Prevention of Cancer: a Global Perspective*, analyzed over 4,500 research studies internationally to develop recommendations on approaches to cancer prevention.⁵ Based on this review, they maintain that as many as three in every four cases of colon and rectal cancers could be prevented with healthy diets.⁶ Both agencies conclude that diets high in fruits, vegetables, and whole grains could help prevent the onset of colorectal cancer.^{5,7}

In the Harvard *Report on Cancer Prevention - Volume 3: Prevention of Colon Cancer in the United States*, the authors do not reach the same conclusions. They report that some studies show a relation between high intakes of vegetables and fruits and lowered risk of colon cancer, but many do not. They report inconclusive evidence regarding whole grains as well. They conclude that whole grains' role in colon cancer prevention is questionable.⁸

OTHER FINDINGS

Other modifiable dietary and lifestyle factors that may be associated with colorectal cancer have been identified by all of the agencies mentioned previously, including: 1) physical activity (decreased risk); 2) high levels of red meats and other animal sources in the diet (increased risk); 3) dietary folic acid and folic acid supplements (decreased risk); 4) obesity (increased risk); 5) alcohol consumption (increased risk); and 6) tobacco use (increased risk). Each factor is summarized in Table 1.

CURRENT RECOMMENDATIONS

Although the effect of high-fiber diets on the prevention of colon and rectal cancers is uncertain, there are other benefits to high-fiber diets. There is little argument about their ability to prevent constipation, hemorrhoids, and diverticular disease. They may also play a role in reducing the risk of heart disease and other types of cancers, such as cancers of the mouth, pharynx, larynx, esophagus, and stomach. Many studies also support the theory that fiber plays a significant role in the control of non-insulin dependent diabetes.

Table 2 offers a summary of the Goals for Nutrition in the Year 2000. These were developed by Willett for the prevention of cancer with other chronic diseases taken into consideration.⁹

The United States Department of Agriculture, the ACS, the National Cancer Institute, and the AICR continue to recommend diets rich in fruits, vegetables, and whole grains and whole-grain products to reduce the risk of chronic diseases, including cancer.

WHAT NOW?

After years of advising patients to adopt high-fiber diets to prevent colon and rectal cancers, what is a health professional to do? Fruits, vegetables, and whole-grains may or may not prevent these cancers. But, presently, there is little argument about other benefits of high-fiber diets, and there is no known harm to eating a diet rich in produce and whole grains. We can only wait to see how the many questions created by years of research will be answered. Until then, advising patients and the public to eat a diet rich in fibrous foods and low in fat is still the best dietary advice we have to prevent chronic diseases, to maintain overall health, and to prevent obesity.

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Judicial Diagnosis

To Sue or Not To Sue: An Attorney's Perspective

Max Wistow, JD, and Rachael Arruda, RN

Before recommending a course of treatment to a patient, the physician has evaluated the risk-benefits - a practice so universal that it frequently becomes automatic, even, at times, unconscious. In 1972 the Rhode Island Supreme Court enunciated a rule in *Wilkinson v. Vesey* which, at the time, seemed innovative. The patient was entitled to know all "material facts" relating to the proposed treatment. "Materiality may be said to be the significance a reasonable person, in what the physician knows or should know is his patient's position, would attach to the disclosed risk or risks in deciding whether to submit or not to submit to surgery or treatment."¹ It is well understood today that the clinician must share such "risk-benefit" information with the patient. Without this information, the patient has not truly given the informed consent required by law.

The physician might be surprised to learn that lawyers who represent plaintiffs in medical malpractice cases conduct a similar risk-benefit ratio analysis, as they decide whether or not to prosecute a claim.

From a lawyer's vantage, the risks and benefits involved in a malpractice lawsuit are, as a practical matter, purely economic. The risks associated with losing the case are obvious. They are the out-of-pocket costs associated with the case and the time value of the legal services expended on behalf of the plaintiff. Since virtually all malpractice cases are prosecuted on a contingent fee basis, the value of the legal services - if lost - is a loss only to plaintiff's counsel. Few plaintiffs (especially ones who have been seriously injured) can bear or even reimburse over time the out-of-pocket expenses run up during the case. Consequently, unless there is a recovery of funds from which to satisfy these out-of-pocket expenses, these too will be borne by plaintiff's counsel. Since the typical malpractice case will involve out-of-pocket expenses of \$50,000 to \$100,000 or more (in addition to the value of the lawyer's time), a lost case represents a significant downside risk.

The investment is large because multiple experts are often needed to prove the claims: at least one expert to establish negligence, another possibly to establish causation (i.e., the link between the negligence and the injury). In addition, economists and rehabilitation experts are often engaged to establish future damages. The attorney must review and become expert in the medical literature on the particular subject, multiple depositions are required, and often voluminous records must be purchased and mastered in order to evaluate and prepare the case.

Medical malpractice cases are almost never settled on a

nuisance value basis. Settlement before trial occurs only where discovery has demonstrated a compelling case for the plaintiff and where plaintiff's settlement demand represents an attractive proposal for the insurer using its own risk-benefit analysis. Whether or not the professional liability policy requires the insured's consent as a condition to settlement, a lawyer who takes on a malpractice case must assume that the case will go to trial and must be prepared to underwrite the costs and expense of trial and appeal.

If the case is to be undertaken, the perceived conomic benefit must exceed the possible economic loss, and it must do so on a risk-adjusted basis.

In most instances, the risk of bringing a case to an unsuccessful conclusion is all on the patient/plaintiff's counsel. The plaintiff has for all practical purposes only potential benefits to be gained. The only time when the risk-benefit analysis realistically applies to the plaintiff is when the medical practitioner or institution offers to settle. At that point the plaintiff weighs the proposed settlement against the possible trial award. What is the relative risk of a smaller (or no) recovery as weighed against the benefit of an award higher than the amount offered in settlement? The answer involves complex variables that include not only the actual perceived risks and benefits but the client's willingness to "gamble" the amount offered. Depending on background and personality, some clients are simply unable to reject an offer, even when rejection might be prudent from a strict probability assessment. For example, a plaintiff might be unwilling to risk losing an available net proceeds equal to \$500,000 even if advised and believing that the probable net proceeds from a verdict in their favor would range from \$1-2 million and that there was a 75% probability of such an outcome. In other words, the plaintiff has made a personal decision that s/he is unwilling to risk \$500,000 even though actuarially the fair settlement value is \$750,000 - \$1,000,000 (75% x \$1-2 million). Whatever counsel's recommendation, the decision will be the plaintiff's, as it would be in choosing the medical treatment.

Once the lawyer has accepted the case, the decision whether or not to settle, and, if so, at what amount cannot be made without the plaintiff/client's informed consent.

The decision by counsel of whether or not to take the case in the first place is affected by the relative negatives associated with this type of case. Settlements or verdicts come only after large expenditures of time and money. Against these is to be weighted the contingent fee - a percentage of the recovery.

Thus, the potential damages to be obtained for an indi-

vidual who has suffered a comparatively minor injury may not justify the substantial outlay of time and out-of-pocket expense necessary to prosecute the claim even when liability (fault) is clear. Conversely, in the case of a severely brain-damaged infant who will require lifetime assistance, the potential damages may likely justify the risk of proceeding with the claim, even where liability may be much more difficult to establish.

The concept is simple. A very strong case of liability with modest damages cannot be as attractive as a case with catastrophic damages even with a smaller likelihood of success. In other words, there is significantly greater value to a case where the verdict might be expected to be about \$1,000,000 even if there is only a 30% chance of that verdict than a case where there is a 90% chance of a \$100,000 verdict.

The legal theories of liability applicable to a medical malpractice claim are the same for all injuries. In order to prove liability on a negligence theory, the plaintiff must establish 1) a deviation from the accepted standard of care; i.e., that the physician failed to exercise the same degree of diligence and skill which is commonly possessed by other members of the profession engaged in the same type of practice, having due regard for the state of scientific knowledge at the time of treatment; and 2) that the deviation proximately caused the complained-of injury.

On occasion, the history provided by the client will contradict the medical records. While most lawyers are skeptical when a client's account differs from the written records, most are willing, in a few appropriate cases, to accept what the client says as accurate. It is, however, especially critical that they carefully evaluate the client's credibility in such cases. It is possible that the record may be in error, or altered. Nothing can make an unattractive case more appealing to a plaintiff's lawyer than the discovery of an alteration in the medical record.

Potential damages consist primarily of out-of-pocket medical expenses, future medical expenses, future lost earning capacity, pain and suffering and the loss of society and companionship sustained by family members. Past medical bills, even if substantial, may not add value to the claim. Rhode Island law provides that, to the extent medical bills were paid by a health insurer, they are not ultimately recoverable. Federal statutory provisions, however, mandate reimbursement of expenditures to both Medicare and Medicaid and, therefore, allow the recovery of those medical expenses.

The more substantial damages generally are compensation for future care and the injury itself. The probable cost of future medical, nursing, custodial care, and loss of future earning capacity will have to be proven by expert testimony. A jury will ultimately decide what is fair compensation for pain, suffering, and disfigurement of the individual now and in the future, and the loss of society and companionship damages for family members to compensate them for their losses as well.

If the damages warrant, all pertinent medical records are examined for evidence of negligence. Even if such evidence is present, it must be shown that the injury was caused by the negligence of the healthcare provider. In this regard, we again consider the strength of the facts supporting causation in light of the medical literature.

A comparison of the records with the existing medical literature may reveal any number of other potential issues. In the case of a missed diagnosis of breast cancer, were the pathology slides interpreted correctly? Was mammography ordered according to ACOG guidelines? Were the mammography films interpreted correctly? Only a thorough and complete review of the records and literature will answer these questions.

Often the in-house legal evaluation will suggest that the matter should be rejected and that expending funds for an expert review is ill-advised. If preliminary evaluation justifies it, however, the case must be reviewed by an expert or experts as needed.

Even expert opinions will need to be evaluated against the medical literature to determine that the opinions are supportable. If the expert's opinion is negative, the injury and the potential damages will determine whether the case warrants a second opinion or even, perhaps, beyond.

The decision whether or not to accept or reject a medical malpractice case is complex. In most instances it is the most



important decision made by plaintiff's counsel during the course of the case. A case that should not have been taken in the first place will be its own punishment to the lawyer who improvidently brought it. This will be small consolation to the medical professional who during the pendency of the case suffers the psychological trauma of being wrongfully accused of malpractice. Conversely, a case that deserves to be brought ultimately will likely provide a financial benefit to the attorney. Most important, however, it will provide the two results for which the tort system exists: the victim of malpractice will receive compensation for the harm; and the health care professional, being reminded in dramatic fashion of the legal consequences of negligence, will have a great incentive to avoid such negligence in the future.

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NINETY YEARS AGO

[AUGUST, 1910]

In "Economic Aspect of Tuberculosis," Edward F. McSweeney, chairman of the Board of Trustees, Boston Consumptive Hospital, delivered "a dirge for millions of dollars lost every year." He calculated that in 1908 tuberculosis cost the state of Rhode Island \$2,169,825 in lost wages (16,534 people ill, 4,133 of them wage-earners losing an average \$525/year) and \$2,700,000 in medical bills (an average family spent \$75 annually on illness and death). To concerns that physicians who practiced "preventive medicine" would lose money, he suggested that even if incomes dropped, most physicians ("the right kind of doctor") would welcome the change. More importantly, he blamed low physician earnings (the average Rhode Island physician earned less than \$1200/year) - not on preventive medicine - "...but the abuse of medical charity which has all but pauperized the medical profession." In New York City, for instance, 3,000-5,0000 people who could have paid a physician a fee were treated free in hospitals - a practice akin to "petty larceny."

In "Cretinism," N.L. Niles, MD, described the "remarkable improvement" after treatment with thyroid extract. Discounting the "artificial" distinction between endemic and sporadic cretinism, he posited early treatment as essential. With Osler's 58 cases, 18 were younger than age 5; and 5 of them were perfectly normal after treatment. Older patients did not fare so well. Dr. Niles described some of his successful treatments of young children.

"In Memory of Edgar Ivory Hanscom, MD, 1872-1910," a eulogy for the assistant physician at the State Hospital for the Insane, traced that young physician's death "to septicemia, resulting from infection received, without doubt, in the round of his professional duties."

FIFTY YEARS AGO

[AUGUST, 1950]

James L. Gamble, MD, Professor of Pediatrics, Harvard Medical School, delivered the 9th Annual Chapin Oration, "Body Fluid and the Rationale of Fluid Therapy," concluding with "a note of admiration of the kidney, which is mainly responsible for [body fluids] integrity."

Charles L. Farrell, MD, in "Medicine's Concern About Licensure of Medical Record Librarians," cautioned against the increasing specialization and credentialing happening throughout medicine: "We can't have all generals in the army of health care."

President Truman had proposed to create a federal department of health, education and security. An Editorial ("Dynamic Democracy") explained the opposition of the Rhode Island Medical Society and the American Medical Association: "[the plan] would create a master organization ready and anxious to take over administration of a national health insurance program."

The Women's Auxiliary to the Rhode Island Medical Society published their Annual Report of Committees. With "every eligible doctor's wife invited to join," last year the Auxiliary welcomed 102 new members.

TWENTY FIVE YEARS AGO

[AUGUST, 1975]

In "A Message from the Dean," Stanley M. Aronson, MD, discussed "Conversations between the Clergy and Practicing Physicians." "The medical profession in the past has typically contended that...clergy should confine their health-related activities to the rendering of solace to the bereaved or the administering of various rites...of faith." Modern physicians, though, recognized a need for more collaboration. The first step toward that collaboration came when Brown Medical School and the University chaplaincy service initiated informal conversations on the interface of medicine and pastoral ministry. That informal conversation expanded to include a variety of clergy representatives and hospital administrators - culminating in the newly-formed Interfaith Health Care Ministry (IHCM), with University Chaplain Charles Baldwin chosen as Director. The IHCM's first tangible project was a recent 5-day internship for clergy: "An Introduction to Hospital Health Care Systems."

Leonard J. Triedman, MD, and Michael J. Weaver, MD, in "A Unified Concept of the Epidemiology and Endocrinology of Breast Cancer," noted that the "Virus is transmitted genetically, but encounters milieus affected by hormonal, environmental and immune factors."

Karl Karlson, MD, PhD, in "Surgical Treatment of Angina Pectoris," urged that "patients with unacceptable morbidity...should be evaluated for ... surgery."

John R. Ruggiano, MD, in "Using Psychiatric Consultation Liaison Service," familiarized readers with the service, including who should initiate the consultation, how to initiate it, and questions to ask.

Robert P. McCombs, MD, in "The Development and Future Prospects of Family Practice Training in Rhode Island," described the upcoming Brown University three-year residency program at Memorial Hospital, including plans to phase out the residency in internal medicine at Memorial.



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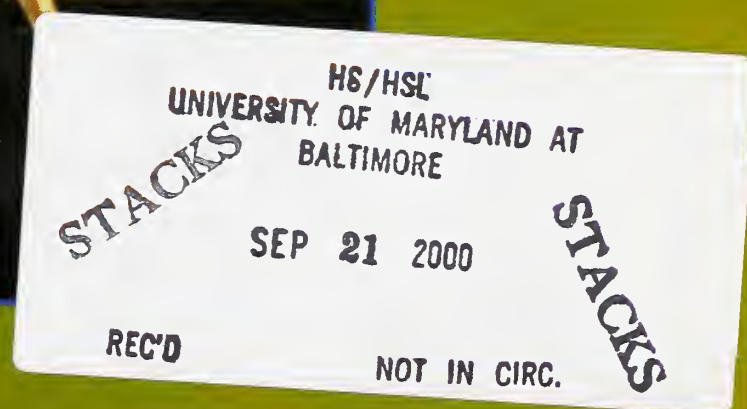
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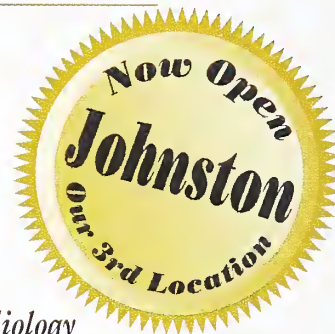
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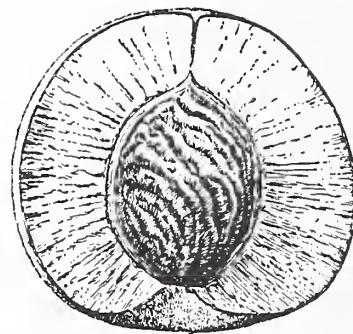
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Who's the Criminal?



Andrew Goldstein, a 30 year-old paranoid schizophrenic who pushed a total stranger to her death in front of a New York City subway, was found guilty of second degree murder and sentenced to jail for 25 years to life, the maximum sentence. It was his second trial. The first ended in a hung jury, the issue being whether he was innocent due to insanity. The murder was never contested.

There are two issues to consider. The first is Goldstein's responsibility for his crime and the second is New York's (city and state). The issue of responsibility for one's actions is a complex one. The determination often falls into a gray zone. In the classic movie, *M*, the main character, played by Peter Lorre, argues that he kills children because he can't help it. He's not a "criminal," he claims. He's "possessed," or "ill," and wishes to be normal. His life of crime tortures him and he'd do anything to be free of his compulsion. His captors, who are professional criminals, are unimpressed.

There are, I believe, three distinct criminally insane pathways towards violent acts. In one scenario a patient, not recognized as potentially violent, has either not reached the mental health system or, under treatment, has not improved. The non-compliant patient represents a different issue. This patient is recognized as violent, improves on medication but then stops his medication and falls out of the treatment system. The third, Goldstein's route, is where the system fails the patient.

Rhode Island had a non compliance case a few years ago when a manic-depressive physician stopped his medication and became increasingly psychotic until killing someone during a minor altercation that mushroomed explosively.

Even in the best of circumstances there are no reliable methods of determining predilection for violence. And

when a psychiatrist makes such a determination, the courts may be required to commit the patient and may rule against the psychiatrist. At issue is the clash between the personal right to refuse treatment versus the clouded insight of a psychotic individual and the safety of the community.

Why do compensated psychotic patients relapse? A schizophrenic patient I knew well explained the seductive nature of his psychosis. As he began to relapse he felt a heightened sense of self-importance that the FBI and the CIA were following his every move and thought. His psychosis thus developed insidiously with a narcissistic delusion that got rapidly out of control. In most patients, however, lack of insight is part of the disease process.

The case of Andrew Goldstein was different. He had been in and out of the hospital multiple times and, although recognized as a threat, was repeatedly released to the community. He had, at times, sought treatment. The state contended that this crime would not have occurred if Goldstein had been punished for his previous crimes. Since psychotic patients frequently go untreated in jails around the country, it is not clear that patients can be both punished and treated, although the forensic units of psychiatric hospitals are clearly designed for cases of both the criminally insane and the insane criminal. Americans have for many years been wary of the "innocent by reason of insanity" conclusion, based on many misunderstandings, deriving from TV shows, and politicians pandering for publicity. It turns out that it is extremely uncommon for the insanity defense to be used; that the defense is rarely successful; that most cases are minor; that most cases are settled out of court because the finding is so obvious.

But what are we to make of a whole

mental health system that fails due to under-funding? Who is responsible? Is New York to blame for Andrew Goldstein's crime? The victim's family and the courts didn't think so. I tend to think it is.

Several years ago a criminal suit was used to overhaul medical housestaff training rules in New York State. This was the result of a malpractice case blamed on sleep deprivation and overwork intrinsic to residency training programs in general. I wonder when New York's and other states' underfunded approach to the Andrew Goldsteins and their victims will be recognized and used to wring some compassion out of a state of non-benign neglect. Recently I learned that Oregon has a lifetime cap on hospitalizations for mental illness. As if all patients can be cured or put into permanent remission. Can these mental health systems be held criminally negligent? Generally the problems are financial and the mental health facilities are woefully underfunded. The responsible parties are the budget-makers. A dollar will only stretch so far.

Are we "better" citizens in Rhode Island that this doesn't happen here? It's true that it doesn't, or at least much less. Fewer patients slip through the cracks. Our mental illness program works far better than most (perhaps all) in the U.S. and I believe it is due less to our funding than it is to the small size of the state and the static nature of the population. Patients get "known" and followed. Health care workers know each other and can, at least, communicate with each other. There is a mental health "community." It is this lack of community that leads to underfunding and lessened responsibility, both by the individual and by the community.

— Joseph H. Friedman, MD

The Art of Prognosis

A Greek legend is told of Apollo, fresh from his victory over Python the serpent, establishing his realm in a sacred grove of trees. He then assumes the shape of a dolphin and captures a crew of Cretan sailors so that they may guard his newly established holy site; and because the sailors saw him as a dolphin, the grove is henceforth called Delphi. In time, a temple called Athene Pronaia [Greek, the foreseeing] is established where dedicated priestesses, as the oracles of Delphi, foretell the future.

The hunger to foretell the future, to offer prophecy, had once been a sacred function restricted to the chosen few. Gradually, though, others acquired arcane skills and then professed themselves to be capable of prophecy. These included professions as recently established as investment counselling and as ancient as medicine. In medicine, though, prophecy is called prognosis [Greek, to know beforehand.] In addition to its responsibility to counsel, medicine has always rested upon three fundamental legs: diagnosis, prognosis and therapy [What ails the patient? What will happen if the ailment remains untreated? What treatment is most appropriate?] And in an earlier era when medicine had only a few meager therapies, the true skill of the physician was his accuracy in foretelling the patient's future.

There are, in the history of medicine, four domains of prediction. The first, requiring little skill beyond outrageous chicanery, is seen when the physician foretells the name and trajectory of a particular illness without having the slightest clue as to the patient's clinical problem or destiny.

A second kind of prediction rests upon the observational skills of the seasoned physician. A child with fever is brought into the office. The examining physician then declares that the child will develop the rash of measles within 48 hours. And, at the end of the assigned interval, the telltale rash does indeed appear. In examining the child, the physician had noted certain spots within the mouth of the ailing child characteristic of an early phase of measles. Measles, therefore, had already arrived but was apparent only to the trained and alert observer. Thus, the physician's declaration becomes a prophecy come true only in the eyes of the credulous.

A third form of medical prediction demands the greatest of clinical skills. In assembling the many items of information derived from the patient's history, the physician can then envisage things to come unless preventive steps are taken. The history, for example, may yield information that both of the patient's parents died of colonic cancer; and the patient, years hence, is then more likely to develop a similar cancer. The presence of certain risk factors such as diabetes allows the physician to tell the patient: "The likelihood that you will develop coronary artery disease is substantially increased unless your diabetes is carefully managed." These risk factors, whether they be imprudent diet, abnormal metabolic states such as diabetes, pathologic physical findings such as high blood pressure or a suggestive hereditary history alert the physician to heightened

possibilities that certain specific diseases may arise in the future. Background data allow the physician to offer recommendations which, if adhered to, may substantially lessen the threat of diseases which have not as yet materialized. These are not remorseless prophecies; rather, they are helpful predictions.

The fourth kind of prediction is the most difficult kind to define. It can be an immensely supportive action, or alternatively, an evil corruption of the patient-physician relationship. An ethical practitioner knows that supportive words and assurances of a favorable outcome are based partially on past experience but also partially on hope. The patient will often interpret the element of hope in the physician's words as a message of certainty, and in some fashion the message will encourage the healing process. It is a kind of verbal placebo which is a crucial part of the human dimension of medicine. But in the hands of a persuasive charlatan, it may go beyond the boundaries of speculation for exploitative ends. The prophesying may replace valid, competent intervention; and the patient eventually suffers.

Medicine employs all four kinds of prophecy: guessing, recognizing premonitory signs, understanding risk factors, and prophecy through willful verbal encouragement. In the distant past, medicine's predictions relied heavily upon whatever external signals were thought to be premonitory. There were no fortune cookies in the Athenian agora or the Roman forum but there were animal entrails to examine, cloud formations to interpret, comets, stars in variously complex configurations and, of course, oracular priestesses who mumbled answers to vital questions.

Gradually, though, physicians came to rely more upon the information refracted through their own senses rather than from cloud movement, occasional comets or the relative positions of the stars. The secular information within inches of the physician's eyes turned out to be of greater predictive value in understanding disease than all of the wondrous happenings in the night skies above. In the words of Cicero: "No one regards what is before his feet; we all gaze at the stars."

A story is told of Sherlock Holmes and Dr. Watson going on a camping trip to west England. It was early autumn, solstice time, when the meteorites were plentiful. After a generous meal and a large bottle of wine, they entered their tent, lay down and went to sleep.

Some hours later, Holmes awakened and nudged his faithful friend. "Watson, look up at the sky and tell me what you see." Watson replied: "I see millions of stars." And Holmes said: "What does that tell you?" Watson pondered a moment and then answered: "It tells me that there are millions of galaxies and, potentially, billions of planets; astrologically, I observe that Saturn is in Leo; horologically I deduce that it is about 3 AM; and theologically, I can see that we are but small and insignificant parts of the universe. Holmes, what does it tell you?"

Holmes was silent for a moment and then he spoke: "Watson, you credulous soul, someone has stolen our tent."

— Stanley M. Aronson, MD

The Changing Economics of Medicine: A Rhode Island Snapshot

John J. Cronan, MD

Changes in the economics of healthcare have been relentless, heartless and determined independent of quality impact. Physicians, often the last to be consulted, are not "in the loop" for any discussion regarding changes in medical care precipitated by economics. My perception may be somewhat biased and the viewpoint slanted since I practice specialty medicine, Diagnostic Imaging, in a large single specialty group. While I am concerned with a hospital practice, my group, Rhode Island Medical Imaging, spends a significant part of its effort in private practice outpatient care. My group has been swept by incessant and often unimaginable cuts and changes in reimbursement, as have all the physicians in the state.

No health practitioner that I know of doubts that our healthcare system is in trouble. There are insufficient dollars in the system to make it function for the level of care expected by patients and desired by most practitioners. The middle-class population of this country assumes healthcare is a right, similar to life, liberty and the pursuit of happiness. This expectation has developed without any commitment of dollars to make it happen and similarly with the expectation that medical care will be perfect and the outcome totally satisfactory. The patient population receiving this medical care in most cases does not actually pay for the service rendered. Most medical care is paid by health insurance provided by the employer or through the public sector.

As discussed in the first article by Stephen Cha, our healthcare system is based on a "Rube Goldberg-like process" which evolved because providers and the government wanted a private plan and not a national/public plan. It is a system without overall design and without overall or universal coverage.

Most practitioners would glibly answer that medical care is market-driven and based on the free enterprise system. Such a system is attractive to indepen-

dent individuals, like physicians. In reality, the system is more socialistic. The government sets rates via both Medicare and Medicaid and determines the number of physicians and hospitals via reimbursements and legislative control. Similarly, the government sets many standards of care be it immunization or practice standards for hospitals or mammography, etc. In spite of the government control and oversight of the system, reimbursement of the practicing physician is not supported or underwritten by the government. Instead, providers are left to fend for themselves and attempt to achieve reimbursement based on "productivity and efficiency."

Bizarre rules of business and commerce exist in other areas of the healthcare system. When dealing with the insurance industry we have a system in which the individual who purchases the insurance (in most cases the employer/government) is not the individual receiving the medical care. This in turn leads to a separation of the patient from the provider. Note the overwhelming sense of deterioration of the patient/physician relationship recounted in the two generations of practicing surgeons portrayed in the article by Candace Dyer. The frustration expressed at the present bureaucracy vs. the simple days of a half-century ago when a handshake would bind a life-long patient/physician relationship. This is compared to the perverseness of the present system, amplified by insurance companies setting out to control market share only to lose money. Max Powell predicts that the insurance movement will go back to selecting "well patients," avoiding large segments of the population and abandoning the goal of controlling market share. This new business strategy will permit the insurance companies to once again maintain financial solvency.

George Vecchione discusses the paradox of the healthcare system with the focus on economics. He discusses how in this present age of unbridled techno-

logical potential we are saddled with reimbursement which doesn't cover the cost of the service provided. Similarly, as the lesson learned from the insurance companies in this healthcare environment, volume will kill you. George Vecchione's article was sent to me the same week that Lifespan moved to seek arbitration to settle a nursing crisis brought on by inadequate number of nurses nationally. The hospital will be forced to pay significantly more dollars to get more nurses, yet there is a massive nursing shortage. Paying extra dollars to move nurses around won't solve anyone's problems. The shortage of nurses has become glaring because, as job consultants have discussed, hospitals are the 21st Century version of a factory. URI's College of Nursing has had a 50% drop-off in applicants for the 1998-1999 year! Implications for financial solvency for hospitals with these kinds of statistics are staggering. Personnel costs are the number one expense for a health system, and these expenses will skyrocket as money is expended to solve the problem. The shortage of medical personnel reflects a lack of interest in healthcare employment. The field of medicine is unattractive for many young people.

Patricia Nolan discusses many of the issues facing the state healthcare systems. The system is certainly underfunded. I would ask where are "the tobacco dollars?" These dollars would have done wonders to stabilize our precarious health system. The insurers have begun the process of selecting patients, which will indeed ultimately lead to an increase of patients in the public sector. At some point, only the well or the healthy will be in private insurance and the remainder in RIte Care.

These economic changes have also hammered medical education. Stephen Smith points out that with increased pressure to produce income, teaching has become less of a priority. Patients must be seen in order to generate a salary. From the viewpoint of a medical student, there

is perceived to be a lack of interest in education at a time when they are paying over \$30,000 a year tuition and many are graduating with over \$100,000 in debt. With this negative economic environment and the overall precarious picture for medicine, it is no wonder that applications to medical schools have decreased for the third year in a row. Rock stars, professional athletes, web page designers, financial consultants are all compensated in a manner that makes their careers look very interesting to younger people. Until physicians are compensated based upon their education, technical skills and time commitment, it appears that this downward trend of interest in medicine will certainly continue.

What I find most interesting is the absence of concern by the public for the problems effecting medicine. Similarly, even on the political scene, during an election year, there is little discussed about the crisis in medical care.

Peter Phipps, a Deputy Managing Editor of *The Providence Journal*, writes on a regular basis in the Sunday Business

Section about the local problems of medical care. He observes the crisis facing medical care and the inability to determine a "scorecard." He perhaps typifies the "educated consumer" in this present day and age. You sense someone ambivalent toward their physician with an admonition of "caveat emptor." The lack of trust defined by Candace Dyer is rampant in Mr. Phipps' article. As he points out, the physician's request, "trust me," won't cut it anymore. The expectations of the population are enormous. You perceive that the art of medicine is lost, and instead there is a demand for perfection and the erosion of trust. These elements develop an enzymatic process for further malpractice suits.

There are no solutions to the economic problems presented in this issue of *Medicine & Health/Rhode Island*. This issue was developed to provide thought and discussion regarding our local health scene. While physicians simplistically wish to care for patients and not argue with insurers or fill out forms, there is no immediate change foreseen on the

horizon. Participation in the present medical environment evokes the old adage "It's only work when you would rather be doing something else." Until approximately five years ago, I never thought any aspect of medical care could be work. Unfortunately, the association of my daily efforts with the concept of work now occurs too frequently. This mindset is driven by changing healthcare economics.

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The Development of Health Insurance

Stephen Cha, MD

Few would purposefully design our present insurance system: patch work employment-based for middle and upper income, then government-based for elderly, disabled and poor. Additionally, our system spends more, and covers a smaller fraction of the population than any other nation.¹ Yet it is this convoluted system, developed from a series of rational decisions and events, that makes for a fascinating if not tragic story of bizarre evolution.

OVERALL TRENDS

Two distinctive trends have helped shape the development of health insurance over the course of this century. First, medicine has steadily grown both in efficacy and expense. At the turn of the century health insurance was rare both because of the limited scope of medicine as well as the relatively low expense of therapies.

The first forms of private health in-

surance in 1847 covered only lost income, not medical costs, reflecting the dominant worries over sickness.² As the scope of health care grew, institutions such as private insurance were implemented in order to accommodate the new demands placed on the system.

Secondly, the providers historically opposed public-based coverage. While public-based coverage dominates most other countries, the provider and other interest groups in this country fended off every proposal for public-based coverage, instead reluctantly supporting private proposals. Eventually, the directions of these plans spun out of provider control. This pattern showed itself in the formation of BC/BS, and in the passage of Medicare. In contrast, consumers drove the development of health insurance in European nations, creating much different systems with vastly different incentives and priorities.³

Abbreviations Used:

AHA	American Hospital Association
HMO	health maintenance organization
NLRB	National Labor Relations Board
PPO	preferred provider organization

The issue is not that providers purposefully created a favorable system, but rather that a provider-based system reflects the legitimate priorities of providers over the legitimate priorities of other groups.

THE BIRTH OF BLUE CROSS

In the late 1920s, two changes took place that helped create Blue Cross. First, health care had major advances, such as antibiotics and the advent of modern surgery with the development of anesthesia and antiseptics.⁴ Accordingly, hospital expenditures rose to \$5.36 per U.S. resident (whether hospitalized or not) per year—while not a large figure by today's

standards, this figure reflects significant hospital expenses.⁵ Second, the Great Depression took hold and private hospital beds began to go unfilled as fewer individuals could afford hospital care. As of 1931 private hospital occupancy declined to 62%.³ This reduction left hospitals in search of a solution. According to Sylvia Law, "Blue Cross is the child of the Depression and the American Hospital Association." It was developed to keep the hospitals full.

In 1929, Dr. Justin Ford Kimball of Baylor Hospital responded to these losses by offering 1,250 Dallas schoolteachers twenty-one days of semiprivate care in a twelve-month period for fifty cents a month. This simple plan established some of the basic principles of health insurance that are still in use today. The plan was conceived as a hospital service benefit—the only other types of insurance that existed at the time were indemnity plans, reimbursing cash only rather than a service benefit. Though providers were initially opposed, these plans were largely designed to protect the providers' losses and ensure their financial stability.

Under favorable tax conditions, and powerful foundation support, the AHA established the Committee on Hospital Service, which eventually grew to become Blue Cross. In 1939, the success of this plan spurred the California Medical Association to form the beginnings of Blue Shield, a parallel structure for physicians.

WORLD WAR II: THE ENTRENCHMENT OF EMPLOYER-BASED HEALTH INSURANCE

Blue Cross grew steadily in the 1930s, covering 1.4 million people in 1938, with private insurance covering an additional 0.1 million. However, by 1951, the insurance industry exploded, with Blue Cross enrolling 37.4 million. Simultaneously private insurance surpassed Blue Cross, covering another 40 million.⁶ This growth was directly tied to a series of wartime government policies and rulings that effectively established employer-based coverage as our dominant form of insurance.

From 1939 to 1944, the GNP had more than doubled, and unemployment fell by a factor of 14.⁵ Despite this wartime economic boom, the federal government instituted price stabilization

along with a wage freeze to prevent price escalation on key goods. The American worker looked for other ways to benefit from the economy, and a series of events made health care an ideal place to gain. Beginning with a ruling by the War Labor Board which allowed changes in health benefits during this wage freeze, there were additional tax advantages if benefits were substituted for wage increases. Essentially neither party was taxed on health benefits, while wages were taxed on both ends. Finally, the National Labor Relations Board (NLRB) and the Supreme Court implemented a series of decisions that made health insurance a legitimate matter for collective bargaining. This shift made health benefits not simply another issue to discuss, because any refusal to bargain over them represented unfair labor practices. Unions began pushing for health benefits to ensure their membership and also to provide an avenue to pursue health care without fighting an uphill battle on national health insurance.

*In 1929, Dr. Justin Ford
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As a result, from 1939 to 1951, the number of individuals with Blue Cross or private insurance grew by a factor of 50. Employment based health insurance was now a fixture of the US system, largely due to decisions that were not based on health care. This occurred during a time when medical technology was still limited—ventilators did not exist (invented in 1955) and therapy for a heart attack largely consisted of watching and waiting. As health care became more expensive, the employer-based system began to chafe at these commitments which were made during the war.

MANAGED CARE AS COST CONTROL

Managed care, created before Blue Cross in the 1930s, produced the first prepaid group practices. However, most of these efforts fizzled under strong provider opposition, with a few notable exceptions such as Group Health of Puget Sound and Kaiser-Permanente. Interest renewed in the late 1960s and 70s when health maintenance organizations were viewed as the answer to cost escalation. Provider opposition was still strong, but President Nixon passed the HMO Act in 1973, authorizing \$200 million in federal funds to establish and develop HMOs over five years.

During the 1980s it was no longer government and policy experts worried about cost escalation, but American manufacturers and employers that complained about the competitive disadvantage of US health care expenditures. This new demand on cost control created the conditions for managed care to grow, from 10.2 million enrolled in 1981 to 38.6 million in 1991.⁷ In 1998, preferred provider organizations (PPOs) surpassed HMOs as the plan type with the largest market share, with enrollment in managed care at 86% of overall enrollment in job-based plans.⁸ Yet these efforts have still not had the kind of cost control that some initially hoped for.

CONCLUSIONS

Many of the problems with the US employer-based health insurance system might have developed regardless of this history. For instance, the high cost of the US health care may reflect American attitudes more than any history of provider-dominated development. Yet perhaps what is most distinctive about the American health insurance system is what is missing: the lack of an overall design and the lack of universal coverage. These holes reflect the arbitrary nature of the development of our system.

Employer-based coverage has always been more effective for certain segments of the population, and for those groups it was quite adequate. However, employment-based coverage has declined, with the percentage of non-elderly Americans covered by job-based insurance declining from 71% to 64% from 1977 to 1996.⁷ Rising health insurance costs, decreasing real wages for low-skill work-

ers, and increase in cost-sharing by employers are all creating a crisis in the employment-based system. Continuing shifts in the nature of the economy will exacerbate these problems.

Providers have dominated much of the development of our health insurance system. Providers today and consumers alike share frustrations as third party agents gain a more prominent role. The changing economy allows more of the middle class to be affected by the lack of coverage as well. These changing dynamics create a possibility for new alliances to help repair our patchwork system of coverage.



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The Present Status of Health Care in Rhode Island from the Insurance Intermediary

Max Powell

The purpose of this article is to put forth a perspective on how recent economic changes have affected the insurance component of the health care system. While the focus is on the present, rather than history, there will be references to previous trends or business strategies to aid understanding of how environmental forces are shaping change in the health insurance industry today.

It will not come as news to anyone that the health insurance industry has recently experienced a difficult period financially, and this downturn was particularly pronounced in Rhode Island. The Rhode Island decline began in 1995 when the combined pre-tax income of the five principal competitors dropped to \$27.6 million, from \$63.6 million in the previous year. This negative trend culminated in a combined pre-tax loss of \$79.4 million in 1998.

A number of factors contributed to these trends, but foremost among them was the drive for market share in the commercial (employer-based) business seg-

ment, and the price competition that resulted. Prescription drugs emerged as a major driver on the cost side of the equation. Efforts directed at utilization management and provider contracting were successful in producing more moderate cost increases in other components of medical cost.

The rapid expansion of health plans into the Medicare Risk business segment by many insurers, both nationally and locally, has also been a significant contributor to the negative financial trends, thanks to cost reduction strategies contained in the Balanced Budget Act (BBA).

The health insurers began to experience a turnaround in financial performance in 1999. The four principal insurers active in the Rhode Island market as of December 31, 1999 produced combined pre-tax income of \$6.2 million for that year. These positive trends have continued into the current year: this same indicator increased to \$13.5 million for the first quarter alone. These results would have been even better but for the significant losses which persisted

Abbreviations Used:

BBA Balanced Budget Act

for the Medicare Risk line of business, at least through 1999.

These improved financial trends came too late to save one long-time competitor, and a promising new competitor, in Rhode Island. Both Harvard Pilgrim Healthcare of New England and Tufts Health Plan have exited the market. Aetna/US Healthcare is renewing efforts to enter the market, but it is too soon to predict success. For the present, if one recognizes that Blue Cross and Blue Chip operate under a common management and business strategy, the Rhode Island commercial market has been reduced to two dominant competitors.

Both purchasers and providers of health care have an interest in how this financial turnaround has been accomplished and, more importantly, how it will be perpetuated. Each insurer has a unique set of strategies, but some general trends emerge. We may be coming full circle.

In order to achieve financial goals, the business of "Health Insurance" has historically relied upon principles common to any line of insurance. Specifically, risk assessment and pricing of each customer accordingly. While Blue Cross plans held out as long as they could with the practice of community rating, the industry in general concentrated more on the quality of the book of business rather than maximizing market share (by offering attractive prices to the people who are least likely to use health care services).

There was little effort at controlling costs through utilization management, and only Blue Cross plans were in a position to control costs through provider contracting. If costs went up, rates went up correspondingly. In many cases, insurers shifted risk to employers through various forms of self-insurance arrangements. The insurance carriers truly were "fiscal intermediaries".

The rapid growth of HMOs and the various models of managed care that emulated them transitioned us into the business of the "Health Plans". The primary focus shifted to cost control as the means of achieving financial goals. Utilization management became an important cost control strategy, and generated huge investments in the information technology to support it. Provider contracting techniques required the use of selective provider networks, and an increased emphasis on membership volume, in order to maximize bargaining leverage aimed at reducing unit costs. Accordingly, market share became a more important issue in health plan strategies, and underwriting (risk selection) was de-emphasized.

These managed care strategies, aimed at controlling costs, along with the perceived need to gain the market share necessary to support them, ushered in a period of relative rate stability (many would say at the expense of providers). In the most recent years, even quality of care comparisons began to emerge as a competitive factor aimed at attracting more members, e.g. the HEDIS measures and other "report card" comparisons of performance regarding access to health care services.

In general, purchasers still support the concepts of managed care. However,

providers, patients, and public policy makers have increasingly sought to put parameters around managed care functions. The increased threat of exposure to legal liability has motivated some health plans to reduce the intensity of the intervention strategies involved with managing utilization. There seems to be little more that can be squeezed from provider contracting, as hospital systems become more organized to increase their own bargaining position. Similarly, physician reimbursement has been reduced to levels which threaten the viability of physician practices.

At some point in the future, public policy makers may conclude that the only people not in public programs are the lowest utilizers of health care and, for this reason, their inclusion would not add much in the way of additional cost.



In short, it seems that much of the public would prefer that the health plans once again assume their former role as "fiscal intermediaries" and return to the "health insurance" business. Perhaps they are getting the message and deciding to "make their money the old fashioned way" – by re-emphasizing the role of pricing and risk selection to be at least on a par with strategies to control cost.

In the last eighteen months we have seen a dramatic increase in health insurance rates, particularly among smaller groups and those whose employees are in older more risk-prone age brackets. Underwriting standards and auditing processes are being strengthened. Market share considerations are no longer driving point-of-sale negotiations as much as are risk assessment and the need for adequate pricing. Counties with inadequate Medicare Risk reimbursement rates are being abandoned. With only

two dominant competitors remaining in the Rhode Island commercial market, the insurers are positioned to acquire business on terms which support their goals.

It is always risky to predict the future. However, two inter-related dynamics seem nearly inevitable.

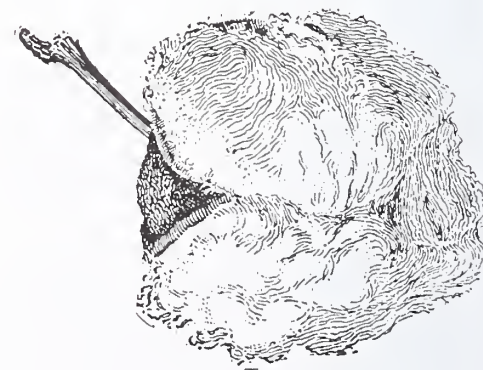
First, as the health plans become increasingly frustrated with their ability to control costs, due to regulatory restrictions or changes in the balance of forces in the market place, they will rely more heavily on the traditional strategies of risk selection and pricing to achieve their financial goals.

The development of this new paradigm will lead to a shift of the population with higher health service utilization from the private sector to publicly funded programs. For example, we are already hearing debate about lowering the Medicare eligibility age down to age 55 (at least on a buy-in basis) as the 55 to 65 age segment becomes priced out of the private market. At some point in the future, public policy makers may conclude that the only people not in public programs are the lowest utilizers of health care and, for this reason, their inclusion would not add much in the way of additional cost. This would certainly become a powerful argument for the advocates of a fully publicly funded National Health Insurance program.

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A Practicing Physician's Perspective

Candace L. Dyer, MD

My father and I collectively have over fifty years' experience practicing general surgery. My dad practiced from 1952 until 1995, and I have been practicing since 1985. Much of the following is gleaned from our personal experiences and his recollection of "times gone by." From a physician's point of view, I do believe, in many ways, they were truly the "good ole days."

When my dad went into practice in 1952, I was just a twinkle in his eye! He joined another local surgeon, who gave him three months free rent as an incentive to join him. Thereafter he paid \$45 per month for a four-room office in Pawtuxet Village, with a sloping floor! One secretary handled all the bookings and billings, and she would also pinch hit as a "nurse" when an assistant was required for an office procedure. Office visits were usually \$5, but ranged from zero to \$8. Most patients had no insurance, and procedures were done for a fee agreed upon between the patient and the surgeon. Most patients kept their word and paid promptly. If they could not afford the fee, they might offer a chicken, fruits, vegetables or some other bartered exchange for services.

When medical insurance arrived in Rhode Island, it was for the most part in the form of Blue Cross/Blue Shield. Physicians were allowed to charge above the insurance allowable limits, but rarely did. The top surgical fee at the time was \$225 for a gastrectomy, colectomy, or some other major procedure. A cholecystectomy brought \$150, and an appendectomy or hernia, \$100. A patient's ability to pay was determined by the "front office" or the sole secretary who would arrange for payment schedules in \$5 packets. There was very little paper work, and the insurance companies required little data, usually just the date and type of service. Denials were not heard of!

Professional liability was not a con-

cern of most physicians, though they did carry a modest amount of malpractice coverage with premiums costing in the range of \$500.00 or less for surgeons. Defensive medicine was not a familiar concept until much later.

Office overhead was about 15%. Office hours were afternoons and evenings. Many minor procedures were done routinely, and the secretary rarely was present for the evening shifts.

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Times have changed! Some of the changes have been painful. Many of the painful changes have come about because physicians tend to focus on caring for patients rather than on keeping the books. Physicians' collective neglect of "the business of medicine" has made them easy prey for payers — who are no longer the patients but their insurance companies or the government. These entities have taken advantage of physicians' storied lack of business acumen.

Overhead in medical practices has grown exponentially, from 15% to about 40%. Our staff now outnumbers physicians by almost 2:1, and 75% of their time is dedicated to collecting money - claims processing, billing, prior authorizations, verification of covered services, etc. Many forms are required to credential and recredential doctors with the various insurance companies, and different plans, and while the data requested are always the same, the requisite format is always different. This takes an inordinate amount of staff time. Even when we file claims electronically, they must be checked, rechecked and

resubmitted, often for reasons that never become clear.

The need for more thorough documentation has also placed an increased burden on practices. No longer do insurers or Medicare take "our word" for services rendered (or proposed). Rather, we must document in detail, and even then we are sometimes denied payment. Until recently, one insurer was routinely and arbitrarily "downcoding" all 4 and 5 levels of care to level 3; now this insurer does not bother to downcode - it just reimburses 4s and 5s at the level 3 rate!

When I first went into practice in 1985, our office visit fee was \$25. It took nearly an act of Congress for me to get my father to agree to an increase to \$35! Now we are all supposed to have differential levels and fees according to the severity and complexity involved and we must justify this with "appropriate" documentation. Fear of being accused of fraud results in many physicians' undercoding. Coding seminars are now routine conferences attended by doctors and their staff. Medicare also wants us to factor in the time element, i.e., how long it takes us to evaluate a patient, but I think this is fallacious. Some physicians accomplish the same thing in much less time and so end up being penalized for their efficiency!

As the American "right to sue" has become ingrained in our society, and personal responsibility takes a back seat, defensive medicine has soared. Diagnostic tests have superseded clinical judgment and are one major reason for the escalation of health care costs throughout this country. "Wait and see" is no longer an option, and it is all too easy to fall prey to the fear of "missing something." This is not to imply that tests are superfluous. Many have made patient care better, more precise and more efficient. But with these advances comes a price tag in terms of costs to the health care system.

My personal view of a better sys-

tem would be one that restores trust and intimacy to the doctor-patient relationship. We must recognize that medicine is both an art and science. No two patients are the same; thus, no two diagnoses are the same. Physicians are human beings trying their best to do what benefits their patients. They are the ones best trained for this work. Neither the insurance companies, nor the government, nor lawyers for that matter, are capable of making daily decisions that affect the lives of the sick.

We must make our system much simpler. Physicians should be practicing medicine and not worrying about the business of medicine. They should

be fairly compensated in accordance with their education, training and skill and time commitment. Society must value health care and realize that it is not free (or even inexpensive). Insurance companies should pay claims and not practice medicine. Quality assessment should be the exclusive province of impartial clinicians. And, competition should be among qualified providers, not based on who will provide services for less.

I am afraid the "good ole days" will never return, but the Medical Society has spent much time this past year working to improve some of the glaring inequities. I believe the pendulum is on

the down swing and, hopefully we will see doctors and patients, once again, in control of the health of our citizenry.

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The View of the Health System – And Why It Matters

George Vecchione

At a recent health care forum, Senator Jack Reed, who lived through discussions on the Congressional level of major reform, cited Charles Dickens to describe the Rhode Island health care system: "It was the best of times; it was the worst of times."

On the one hand, our health system is influenced by factors that are literally transforming the face of health care, and Rhode Island's health care system - if it can navigate the current turbulence and remain intact— stands poised to translate advances in biotechnology, information technology, and biomedical research into a system more efficient, quality-oriented, cost-effective, and outcome-focused.

On the other hand, our health care system, nationally and especially in Rhode Island, finds itself beset with unprecedented challenges: dramatic reductions in public sector support, a volatile and shrinking local insurance market, an older and aging population, diminished borrowing power, an expansive regulatory environment, and the persistent problem of providing care and coverage to those without private insurance.

The federal Balanced Budget Act

of 1997 slashed payments to health care providers, and teaching hospitals were among those hardest hit. The Health Insurance Portability and Accountability Act of 1996 requires health care institutions to adopt a common set of standards and requirements for securing electronic information, including privacy and security requirements, that bring with them attendant costs in information technology and logistics.

When assessing Rhode Island's overall health care costs, the impact of demographics must be considered. Rhode Island has one of the oldest populations in the country, with a high percentage of our citizens over the age of 65. We also have the highest percentage of what demographers refer to as the "old old": people over 85. As people age, they require more frequent and more complicated health care services. Consequently, in Rhode Island while hospital costs are lower than the national average, our costs per person are higher than average due to higher utilization.

To complicate matters further, the volatile insurance market in Rhode Island, after the failure of Harvard Pilgrim Rhode Island and the retreat of Tufts Health Plan,

leaves providers with fewer insurers with whom to contract - increasing the risk that payments will be insufficient to cover costs and overhead. Increased reliance on managed care, which in Rhode Island also includes a high concentration of Medicare recipients insured through managed care, has been one response to the strain insurers, employers and consumers all feel. There is no question that consumers and businesses are increasingly price-sensitive, and question both care protocols as well as costs in today's health care system. These trends are particularly troubling to non-profit teaching institutions, for whom a certain amount of cost is driven by their "public good" missions of caring for the uninsured, subsidizing teaching and research, and often caring for the sickest patients.

In the face of this strain, health care providers cannot afford to sit still, since future enhancements of patient care and health system efficiency rely on new innovations and new investments. Providers throughout Rhode Island are focusing on creating collaborative, patient-centered models to improve the patient experience, reduce errors, and achieve good outcomes.

All hospitals in Rhode Island, for example, are working with the Department of Health to implement the clinical and quality outcomes reporting called for in legislation advanced by Lt. Governor Charles Fogarty.

As an example of the opportunity, I cite Lifespan's investments in communications and computing infrastructure to arm the doctors and nurses who work at our

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institutions with 21st Century tools for recording, sharing and interpreting patient information. Lifespan has invested \$44 million in information technology enhancements in the last four years alone. Most of these expenditures have been aimed at improving patient care by bringing more information to the bedside, and improving communication between providers to make care as seamless, collaborative and coordinated as possible. For instance, we are building a comprehensive patient index consisting of basic data about all patients who come through any Lifespan facility, so that upon a return visit, providers on site will have access to previous illness and treatment interactions. We are also making electronic clinical records available to physicians through a high-speed connection, allowing for security and privacy of patient data and near-instant access for community physicians who want to follow hospitalized patients from their offices outside the hospital. We also built a single communications network to share information among our partners - a faster, more convenient sharing of resources. Finally, we are about to implement an order entry project which, among a number of clinical care tool enhancements, will allow physicians to access patient-specific information and knowledge bases as they plan next steps in a patient's treatment plan. We are hopeful that these tools will reduce the number and severity of patient errors - a topic that has recently catapulted center stage with lawmakers in Washington and around the country.

Health care providers, particularly research institutions, also must stake a claim in the burgeoning world of biomedical research and genetics and genomics. At Lifespan alone, external research funding grew nearly 57% between 1996 and 1999, from \$21.3 million to \$33.4 million. Since biomedical research is one area in which the Congress, like private entrepreneurs, seems willing to invest more resources, the potential for Rhode Island to continue to grow its biomedical research enterprise, and to create more high-paying jobs, is great. The announcement earlier this year that researchers have fully mapped the human genome carries with it dizzying implications for the future of health care, the efficacy of medicine, the very continued existence of disease as we know it.

The size, shape and character of Rhode Island's health care system will continue to evolve. It is not

yet clear whether key parts will survive the current economic turmoil; there is no better example of this than the current fragility of the home health care industry. Navigating a path through countervailing forces will require a thorough understanding of our health care system: what and where the costs are, what drives them, and why so many parts of the system are losing money. It will also require a better understanding of how government, providers, health care institutions, and insurers can best work together to provide a high-quality, cost-effective solution for patients.

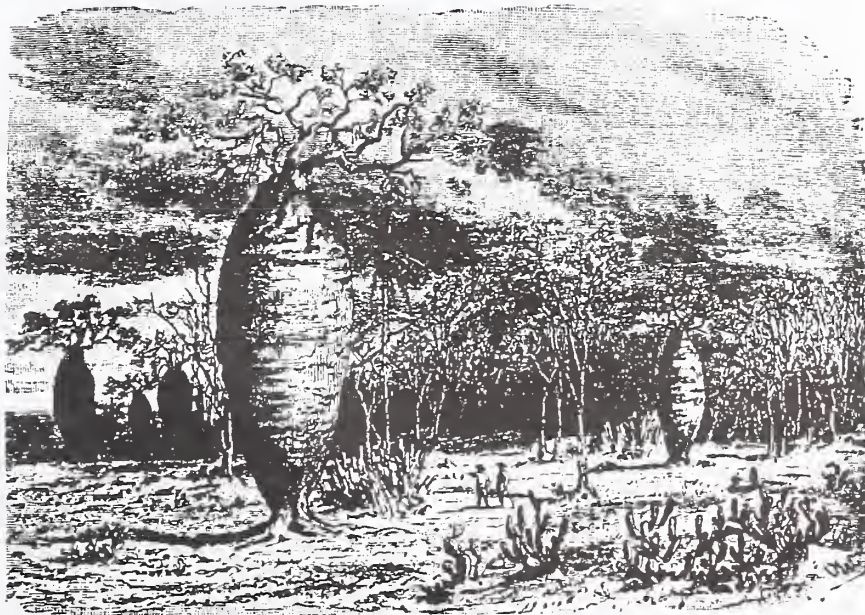
One thing is clear: the stakes are high. Health care is the biggest private sector job producer in Rhode Island, responsible for the paychecks of more than 40,000 Rhode Islanders. Rhode Island teaching hospitals bring in more than \$60 million public and private research

dollars to the state, money that is spent outfitting labs, buying equipment, and paying salaries - all bolstering the Rhode Island economy. The breadth and availability of high quality health care services are a draw to the Ocean State: just ask the patients from Massachusetts, Connecticut and elsewhere who make Rhode Island a net importer of patients. Working together to maintain and advance our system's excellence, and to fix those parts not working optimally, is not only vital to our economy, it is vital to the health care of all Rhode Islanders.

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The State's Viewpoint

Patricia Nolan, MD

Health care is a major responsibility of state government. The state purchases health care and health. State agencies also provide health care services to specific populations. The state is concerned with maintaining adequate quality, providing appropriate access, operating efficiently, and having adequate revenues. At the same time, people's access to health insurance and how much it costs are very important policy and budget concerns for the State. State agencies exercise regulatory authority over health care and health insurance, further affecting the economic basis of medicine. Increasingly, in an effort to encourage "prudent purchasing" and allow market forces to influence cost, quality and accessibility, state regulatory agencies are charged with making information widely available to policy makers, providers and consumers.

The Governor's Advisory Council on Health (GACH) was established to conduct research and analysis on trends in the health care marketplace. Its most recent report¹ examines the health care industry in the Rhode Island economy, concluding that:

- Health Services is the top private sector employer, accounting for 11.3% of total employment and 12.6% of total payroll.
- Employment in health care has grown faster than private sector employment as whole, with particular expansion in residential care, home health and physician offices.
- The federal Medicare program contributed \$1 billion to the Rhode Island economy in 1998, while the federal share of Medicaid and other state health programs was \$543 million.

A funds flow analysis of health expenditures in Rhode Island in 1998² shows that:

- In 1998, total Rhode Island health care expenditures exceeded \$4.66 billion, not including research, construction or training programs.

- Per capita expenditures for health services and supplies increased to \$4,712 in 1998, 19% greater than US per capita expenditures. Consumer out-of-pocket expenditures in Rhode Island were \$847 per capita.
- The largest component of the health care dollar, 36%, is spent for hospital services. However, outpatient care makes up an increasing portion of hospital revenue.
- The largest source of funds for health care services and supplies in Rhode Island was private health insurance (35%), closely followed by federal sources (31%). Consumer out-of-pocket expenditures accounted for 18%.
- Per capita costs associated with hospital services in Rhode Island exceed the US average by more than 20%. Per capita spending for nursing home services exceeds the US average by 30%. The higher proportion of persons over 65 in Rhode Island partly accounts for the higher utilization rates reflected.
- Shifts to Medicare and Medicaid managed care contracting has had a modest impact (approximately \$23 million in 1998) in reducing hospital revenues and in increasing the share of Medicare payments for physician services and prescription drugs. The higher proportion of aged persons and the higher penetration of managed care options in Rhode Island magnify the impact of Medicare policy changes on health care expenditures in the state.

In a separate study,³ the GACH examined whether Rhode Island's health care industry is competitive. The study used health plan costs as a measure of competitiveness, and concluded that premium rates needed to cover the costs of benefits are similar in Boston and Providence. The authors state, "There does not appear to be any underlying competitive cost advantage inherent in the Rhode

Abbreviations Used:

GACH Governor's Advisory Council on Health

Island health care system."

The study also compared unit costs for health care services among Connecticut, Massachusetts and Rhode Island hospitals for Medicare patients. Reimbursement per hospital discharge for the top ten DRGs by volume and by intensity was generally lowest for Rhode Island. Utilization rates were marginally higher in Rhode Island.

Approaching the question of health care services from the perspective of hospital costs, the Department of Health has compared community hospital costs for acute care in Rhode Island with those in New England states and the United States.⁴ In 1998, Rhode Island hospitals had the tenth highest expenses per-capita but the twentieth lowest unit expenses. Reconciling these two apparently conflicting statistics was the fifth highest outpatient utilization in the country.⁵

A review of hospital unit expenses shows that "Rhode Island hospitals incurred \$5,025 in expenses, in aggregate, per adjusted discharge (case-mix adjusted)⁶ - 6% less than the national average of \$5,318, and the least expensive in New England."⁴ This data suggest that higher outpatient hospital utilization is a significant factor in the relatively higher per capita hospital expenses in the state.

Of critical importance to the Rhode Island health care system, in 1998 Rhode Island hospitals received \$4,829 per adjusted discharge against an expense of \$5,025 per adjusted discharge, a result of the payment policies of individual payors and unreimbursed services. In the 2000 legislative session, the hospitals expressed concern over lower revenues because of unpaid co-payments and deductibles and long delays in reimbursement from health insurers. Insurers cited high per capita costs of hospital care and delays in billing as inefficiency.

A central question in Rhode Island in 2000 was how to preserve high levels of insurance coverage at reasonable costs. Despite surveys showing a willingness to offer health insurance to workers in most employment sectors,⁷ there was a major shift away from employer-based health insurance to the public plans in 1999. One major managed care plan failed. A second, smaller plan withdrew from the state, and a third reduced its Medicare managed care benefits. Costs of employer-based premiums increased, and further increases are predicted. Improving and subsidizing the small business health insurance market to control cost and reducing dependence on the public insurance plan are central strategies.

In this environment, widespread disaffection of health professionals is evident. Physicians, other health professionals, clinics, and home health agencies are frustrated. The pressure to practice more efficiently is accompanied by increased administrative demands and slow, inadequate payment. Many practices reported that they are financially strained. The increased cost of practice, including extensive diagnostic and treatment alternatives needing more communication with patients and among health professionals, is not matched by increased reimbursements for time spent. Health professionals resist the myriad reimbursement scales, co-payment and deductible requirements, and approval procedures of the multiple health plans which pay for the care of their patients.

Physicians and other health professionals jockey for autonomy and reimbursement. In an effort to expand reimbursable services, a number of health professionals are seeking or have gained an expanded scope of practice. Changes in the scope of practice of health professionals are seen as encroaching on the physician's professional role.

Health plans seek to limit the number and types of health professionals serving their beneficiaries by developing coherent networks and utilizing benefit management companies, disease managers, and care managers to monitor utilization and improve coordination. The clash of professional autonomy with cost control and utilization reduction measures is seen by patients as a frightening limitation on their ability to obtain needed health

care, to maintain a relationship with a primary physician, and to have health care easily available when they need it.

No single viewpoint on how to meet the competing goals of high quality health care for all persons at an affordable price has emerged. Demands for lower premiums for health insurance, lower costs of health care, and solvency of health insurers are matched by demands for greater benefits and coverage, better reimbursement of providers, higher quality and increased access to care.

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Our attempts to resolve health care financing, access and quality issues for Rhode Island, and the US, in piecemeal fashion have not worked well. A major overhaul of the ways we finance and deliver health care through national health care reform was rejected resoundingly in 1994. How can we respond to these challenges?

The best answer may be akin to the bumper sticker slogan, "Think globally. Act locally." If we can envision a health care system that maximizes participation and quality while minimizing costs, our interim steps may be more productive. In order to develop a shared conception of a successful health care system, I suggest that we need to do the following:

- Emphasize the role of prevention, health promotion, and early detection in reducing the burden of illness of Rhode Islanders;
- Provide as much information as possible about the value and quality of health care services to Rhode Island-

ers;

- Increase monitoring of the quality and access to health services while controlling the cost of monitoring and collecting information, and make the findings easily accessible to all interested persons;
- Support people in their efforts to understand the existing health care system in Rhode Island and to navigate that system successfully;
- Develop and enforce expectations for quality health care, not just minimum standards, in all Rhode Island health care facilities and by all Rhode Island health professionals.

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Economic Effects on Medical Education

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The economic forces prevailing in the medical marketplace affect medical education. Since the first graduates of the Brown University School of Medicine received their medical degrees in 1975, the proportion of the nation's wealth devoted to health care has doubled from about 7% of the gross domestic product to nearly 14%. The rising costs prompted business and government to seek ways to reduce the growth, resulting in the current managed care system. Despite the increased spending for health care, the proportion of uninsured and underinsured Americans grew.

During the same period, concerns about a doctor shortage turned instead to worries about a doctor surplus. The size of the medical faculty grew rapidly despite little growth in the number of medical students. Governmental support for medical education began to erode.

This article describes how these economic forces affect medical education at the level of medical students, residents and fellows, faculty; the medical school, and teaching hospitals.

UNDERGRADUATE MEDICAL EDUCATION

Medical student education takes a back seat to research and service among the three missions of academic medicine. Until recently, implicit cross-subsidization through service and research revenue streams helped support the teaching effort of clinical faculty. The elimination of these cross-subsidies by private and public third-party payers has reduced the willingness of faculty to teach medical students.

Brown Medical School instituted a system to partially compensate full-time hospital-based faculty for teaching in the first two years of medical school, starting with the 1996-97 academic year. However, this system depends on hospital payments to the

Medical School through affiliation agreements. Some teaching hospitals have failed to make those payments because of operating losses, thus preventing payment on behalf of those physicians from those hospitals. Even if all the payments were made, the system does not include teaching in the last two years of medical school and no provision is made for the efforts of voluntary faculty.

If the cutbacks continue as planned for the teaching hospitals in Rhode Island, Medicare payments for medical education will be reduced by as much as \$20 million per year by 2002.



GRADUATE MEDICAL EDUCATION

Brown's residency and fellowship programs have been challenged by the 1997 Balanced Budget Act (BBA), which reduced subsidies for graduate medical education. Medicare payments to teaching hospitals in the form of Direct Graduate Medical Education (DGME) and Indirect Graduate Medical Education (IME) payments have been capped based on the number of residents per institution as of 12/31/96. For us, this has limited the expansion of some GME programs, caused modest cutbacks in others, and thwarted the initiation of new programs since no additional payments are made to the hospitals for positions above the caps.

Additionally, the IME adjustment

Abbreviations Used:

BBA	Balanced Budget Act
DGME	Direct Graduate Medical Education
IME	Indirect Graduate Medical Education

factor will be reduced to 5.5% beginning in 2001, down from 7.7% in 1997. This translates into a 9% reduction in a hospital's 1998 IME payments, increasing to a 34% reduction in the 2002 payments. If the cutbacks continue as planned for the teaching hospitals in Rhode Island, Medicare payments for medical education will be reduced by as much as \$20 million per year by 2002.

Further compounding the problem in Rhode Island has been the high level of enrollment of Medicare recipients in managed care - nearly 58,000. Managed Medicare plans don't contribute to medical education.

FACULTY

All of the academic track faculty in the medical departments are employees of affiliated hospitals or foundations. Under the pressure of lower revenues, hospital administrators looked to the faculty to increase revenue and cover increasing parts of their salary from clinical income. In response, faculty have increased the time devoted to seeing patients, thus reducing other activities. One option was to decrease research time, which could potentially lead to fewer scholarly publications and grant awards. A second option for faculty is to cut back on their teaching activity. The former option has resulted in difficulties with academic promotion for some faculty. The latter option has meant more difficulty in finding preceptors for students.

Increasing clinical activity has led to increased competition for patients between the full-time faculty and the

community physicians on whom the medical school depends for voluntary community-based teaching. This exacerbated "town-gown" friction between the groups. The hospital-based physicians were frustrated because time, formerly used to pursue research and scholarly activities, instead had to be devoted to patient care. The clinical voluntary faculty felt overworked and unappreciated by the medical school.

The medical school has taken two steps in response. One is to develop a clinical-educator track for hospital-based faculty whose main activity is clinical care but who also do extensive clinical teaching. Another step has been the appointment of an associate dean of faculty affairs for clinical voluntary faculty to provide more recognition for the valuable teaching contributions of the community-based private practice faculty and to better integrate them into the larger Brown community.

MEDICAL SCHOOL AND TEACHING HOSPITALS

Brown medical school derives no direct support from the clinical activity of its faculty, nor does it pay any of the clinical faculty salaries. While this arrangement minimizes any financial risk for the university, it also prevents the medical school from playing a substantive role in deciding how hospital resources are used to support the academic program. Not enough attention is being given to the need for creative and energetic leadership in the research and educational activities of faculty.

The establishment of education and research foundations at each of the affiliated institutions is the academic medical center's attempt to support and strengthen the academic activities carried out by Brown faculty. The academic aspirations of the faculty can be clearly articulated and supported with resources necessary to ensure their fulfillment. These foundations serve as the leading instrument for a restructuring of the education and research efforts of the Brown University School of Medicine in partnership with its affiliated hospitals.

Increasing clinical activity has led to increased competition for patients between the full-time faculty and the community physicians on whom the medical school depends for voluntary community-based teaching.



THE FUTURE

Despite the challenges enumerated above, Brown and its affiliated hospitals and community partners are in better shape than many other academic medical centers. In all likelihood, the Balanced Budget Act will be modified this year, buoyed by the good national economy, thus alleviating a good deal of the financial strain on the system. The challenge remains for us to use this expected reprieve to restructure the manner in which medical education is financed in order to weather the next storm that is surely to come.

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The Perspective of a Consumer

Peter Phipps

The health-care crisis keeps pounding at the gates.

The failure of Harvard Pilgrim. Budget-threatening increases in RItE Care, the state's health plan for lower-income families. Medicare defections. A nurses' strike. All within the last year.

No sooner had the state fought off one crisis than it was hit with another.

This last time, it was a matter of life and death.

A walkout by 1,700 nurses and technicians, doctors warned, would have plunged Rhode Island "into an unprecedented health-care crisis."

The hospital's strike plan stretched resources too thin.

There is likely to be delayed treatment," 10 cardiologists wrote, "which will lead to increased suffering for patients and possibly to increased mortality."

By going to arbitration with the nurses, Rhode Island Hospital got through the summer, but it's just a matter of time before the next crisis blows through.

The hospitals are in bad shape. Lifespan, Rhode Island Hospital's parent company, can't pay its bills without dipping into endowment income. It's not alone. Most of New England's major hospitals are losing \$1 million a week, or more.

There's no reason to believe the future will be any better until government addresses the central flaw of our health-care system:

We don't know what works and what's a waste. We're buying blind.

We do know that health care is expensive, and we've been told that it's going to get more expensive with every life-extending advance, but we don't know when we're buying right.

Figuring out the cost of a health plan is hard enough. Balancing cost against quality is impossible.

All we can measure is the money. So we get what we measure: an insurance system that restricts care and denies payment; a delivery system that seems to

work only for the drug companies and a shrinking number of physicians.

Meanwhile, society clings to the illusion that doctors, hospitals and health plans are the same, an erroneous belief that the quality of care has not suffered.

What's a consumer to do?

Of course I know what you'd do. I know who reads *Medicine & Health/Rhode Island*. You'd do what I'd do. You'd call around and find the physician with the best reputation. Then if you were really conscientious you might look at the health department's physician profiles or you might try to find a little information out of the data bases compiled by the Health Care Financing Administration.

Trust me, I'm your doctor, just won't cut it anymore. Consumers need and deserve the data to make informed decisions.



You wouldn't get much hard information. But in a small place like New England, you could probably avoid the really incompetent doctors and stay out of the mismanaged hospitals.

But what if you didn't know whom you know? What if you weren't one of the information elites? Then you'd be at the mercy of a system deathly afraid of letting their customers in on one of the secrets of American health care: some doctors and hospitals are better than others.

Periodically, some state or advocacy group will muster the courage and the financial resources to study mortality rates — medicine's ultimate test. The results are startling. In one national study cited last year by the *Wall Street Journal*, the death rate for esophagus cancer var-

ied from zero to 26% from hospital to hospital. Similarly, a Pennsylvania study found the number of comparably ill stroke patients who died in the hospital ranged from zero to 36%. Finally a study by the National Academy of Sciences concluded that 44,000 to 98,000 Americans die from medical errors each year.

Trust me, I'm your doctor, just won't cut it anymore. Consumers need and deserve the data to make informed decisions. When this data is public, a remarkable thing happens: in case after case, quality improves. As they say at the Rhode Island Department of Education, information works.

Let's look at the numbers from three states, Ohio, Pennsylvania and New York, where risk-adjusted outcomes were reported to the public:

- In New York, the legislature took the medical establishment head on and graded both doctors and hospitals. As a result, 27 poorly performing cardiac surgeons dropped out of the business and the death rate from 1989 to 1996 dropped by about one-third for bypass surgery. In New York, you can sit down at your computer and look up the risk-adjusted mortality rates for the state's hospitals and cardiovascular surgeons. Unfortunately, New York doesn't make the information easy to find. Just look at the length of the URL: <http://www.health.state.ny.us/nysdoh/consumer/heart/homehear.htm>
- In Northeast Ohio, consumers used to be able to pick up a little book that graded the hospitals on usage, mortality rates and patient satisfaction. The mighty Cleveland Clinic pulled the plug on the project. While it lasted, Cleveland Health Quality Choice saved lives and improved hospital procedures. The report from May of 1997, for example, shows those mortality rates for a set of di-

agnoses fell from 6.89 per 100 to 5.72 deaths per 100. Several hospital administrators in Cleveland said the reports alerted them to problems that, under the glare of public scrutiny, they were forced to correct.

- In Pennsylvania, the death rate for heart-bypass surgery plunged nearly 30% from about 4 per 100 in 1990 to almost 2.5 per 100 in 1996 after the state started reporting outcomes. And, according to the Pennsylvania Health Care Cost Containment Council, costs also fell. Pennsylvania's data is a little easier to find (<http://www.phc4.org/>). The problem is that it's dated. Unlike the Cleveland reports that were issued every six months, much of Pennsylvania's bypass data is five years old. That's too old to be much help.

Critics claim that outcome reporting penalizes the best doctors with the toughest cases. And to a degree that may

be true. But still the public needs this data, even if it is not perfect and even if the average consumer won't use it. The record shows that publicizing the data improves quality.

This message seems to have reached Rhode Island. Two years ago, the General Assembly passed a bill submitted by Lt. Gov. Charles Fogarty to get Rhode Island in the game. Committees have been meeting. Consultants have been hired. Lifespan, in announcing its plans to merge with Care New England, last year announced, with some fanfare, that it was "committed to publicly reporting patient care outcomes and quality."

Lifespan even said it would help finance a joint effort with the Department of Health to run a quality health institute. Independently, the health department and the Hospital Association have hired consultants and they've held meetings. The hospital association says it will issue a patient satisfaction report in a year. Consumers will have to wait until 2002 to see outcomes.

If Rhode Island does it right and then sticks with it, the data could help transform the way we buy health care in America. And then, when the next crisis hits, at least we'll know what's worth protecting and what's not.

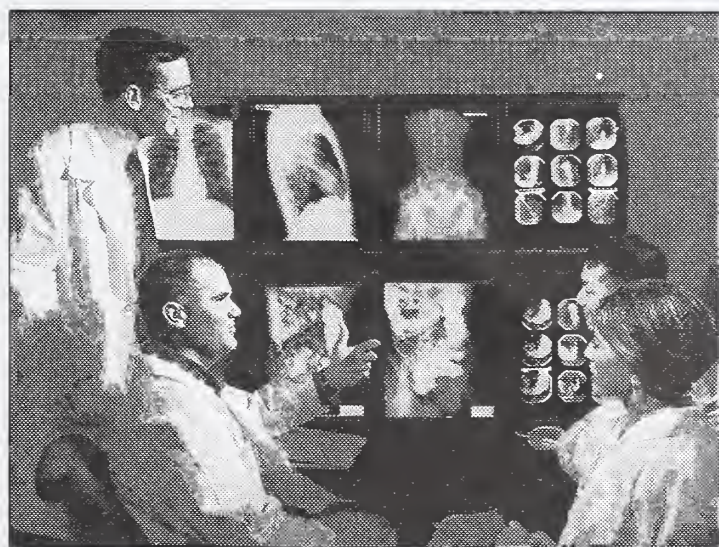
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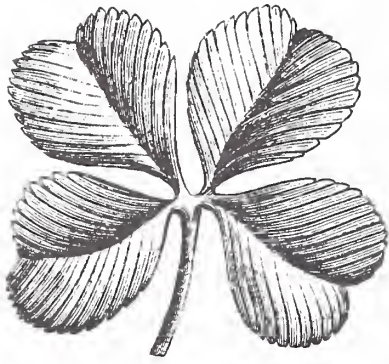
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Medical Myths

Ignorance is preferable to error; and he is less removed from the truth who believes nothing, than he who believes what is wrong. — THOMAS JEFFERSON, Notes on the State of Virginia



Myth: Insulin Sliding Scales Work

Charles B. Kahn, MD

I recently read, "Controlling Hyperglycemia in the Hospital: A Matter of Life and Death" in *Clinical Diabetes*,¹ prompting me to comment on one of the common medical myths; specifically, the myth that "sliding scale insulin therapy is effective and appropriate therapy for managing diabetes in hospitalized patients." The message came through to me loud and clear. There is ample evidence in the literature that hyperglycemia can be a major contributor to morbidity and mortality in hospitalized patients. Levetan¹ reviews this subject well in her article. Sliding scales of insulin therapy do not work and are almost always used inappropriately in the context of the need for glycemic control in hospitalized patients. Queale et al² also provide an excellent review.

The problems with the sliding scale are many. The insulin dose is arbitrarily selected. There is a cut-off below which no insulin is given. Human regular insulin can have a duration of action of 5-10 hours, and the daily intra-person variability can be great. Humalog regular insulin has a more predictable four-hour duration. Absorption of all insulins may be affected by the timing of and site of injections and by the clinical condition of the patient, such as edema and hypotension. The effectiveness of the insulin (i.e. insulin resistance) likewise can be affected, for example, by any infectious or inflammatory processes, glucocorticoid therapy, or catechol-related pressor agents. A major problem is that the timing of blood glucose testing is often written as 7 and 11 a.m. and 3 and 9 p.m. The blood is drawn at the time requested plus or minus 30

minutes, and one to three hours may pass before the results return to the floor. Much may have occurred to a patient with such a delay and yet the insulin order is set by the sliding scale and given when the results return to the floor. This is a retroactive approach to the problem. The sliding scale is written and all too often the physician allows the scale to remain fixed, for the nurse to make the decision, and no review of the efficacy of the scale based upon the blood glucose data is made. The assumption is that the insulin dosage schedule for the sliding scale will take care of the glycemic control and will take one more burden off the shoulders of the physician. This "one size fits all approach" puts the program on a faulty automatic pilot. Data, though, clearly show sliding scales do not work, and thus contribute ad-

versely to the care and outcome of the patient. In my opinion, for most but not all patients in hospital, the sliding scale that is presently used should not be employed in the care of diabetic patients.

Under special circumstances, sliding scales for insulin therapy can be effective, allowing a small window of truth to the myth. Blood glucose testing can be done at very specified intervals but must be carried out at the bedside with a trained person using a reliable glucose meter so that the glucose data will be immediately available. The timing of blood glucose determination will depend upon whether the patient is eating or not. For patients who are on a diet, a 7, 11, 3 and 10 schedule is more appropriate although the timing between the last dosage and the morning breakfast may be excessive, and a glucose test may have to be determined in the middle of the night. For a patient who is npo or on some type of non-intravenous parenteral feeding, glucose values need to be determined every four to six hours depending upon whether a rapid acting Humalog type insulin or the standard human regular insulin is used.

The sliding scale for insulin dosage should be established based upon more specific information for the individual patient and not simply as one-size fits all approach. A starting point can be based on the total dosage of insulin required prior to the patient's hospitalization. This can give the physician some idea of the degree of insulin sensitivity and/or resistance. Another approach would be to use a dosage schedule based upon 0.1 units per kilogram body weight for a glucose

I recommend the use of sliding scales as the primary mode of insulin administration almost exclusively for medical and surgical intensive care units and the coronary care unit where bedside blood glucose determinations are available and nursing care is more intensive.



estimated to be in the range of 200-250 mg/dl. An example would be a 70 kilogram patient would need approximately 7 units of regular insulin for this blood glucose range. One would then reduce the scale by one or two units per 50 mg/dl below this range and the same increase above this range. I recently heard of a schedule based upon a formula of the blood glucose minus 100 divided by 30, 40, or 50. The higher denominator number would be for patients more sensitive to insulin, the lower number for those more resistant.

It is very important to have a minimum period of time for which the patient is not covered by at least some insulin. I prefer to begin the schedule at 50-100 mg/dl as a starting point and increase the established schedule by the number of units determined for every 50 mg/dl above this range. It is also important to continue to give insulin at the specified dosage when the patient is euglycemic. Below 50 mg/dl the patient is in the hypoglycemic range, and it is appropriate to withhold insulin therapy. However, rather than waiting four to six hours for the next determination, I would recommend rechecking the blood glucose value in two hours and intervening at that point if necessary. Given the circumstances I have outlined, I recommend the use of

sliding scales as the primary mode of insulin administration almost exclusively for medical and surgical intensive care units and the coronary care unit where bedside blood glucose determinations are available and nursing care is more intensive. More importantly, under the circumstance in which a sliding scale may be utilized for an intensive care patient, a continuous intravenous insulin drip may actually be more appropriate and easier to manage.

The approach that I recommend for most insulin requiring patients in hospital is to use a longer acting basal insulin so that there is no gap in insulin coverage. An intermediate acting insulin, particularly NPH insulin, is the method of choice and usually must be administered twice-daily at breakfast and bedtime, for patients on a diet and every 12 hours for those who are *npo*. The initial NPH insulin dosage is arbitrary, but I would recommend giving half of the NPH dosage utilized prior to the patient's hospitalization. This can be used for both the a.m. and p.m. NPH dosage. If the patient was on a single injection of NPH insulin, then half of the calculated morning dosage can be used in the p.m. Once the basal insulin order is established, it is now appropriate to use a regular insulin sliding scale following the guidelines that have been outlined.

It is very important to reemphasize that the value of such a recommendation is that there is no time when the patient escapes from insulin coverage and that if appropriately selected the sliding scale will adjust to the needs of the patient and the effect of the peak action of the NPH insulin. Equally important to this and any sliding scale program is to reevaluate the NPH and/or regular insulin sliding scale schedule at least daily and probably, under more unstable circumstances, twice daily.

The presently used mythical, retroactive protocol does not work. I have outlined a proactive, anticipatory protocol which will improve the glycemic control. Improved glycemic control in a hospitalized patient is achievable under the present practice guidelines, based upon available experience and evidence, and should be mandatory.

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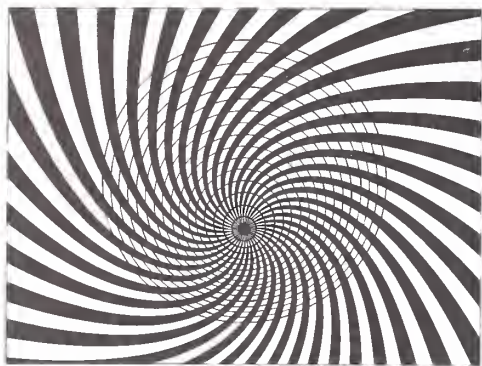
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IMAGES IN MEDICINE

Endovascular Repair of Abdominal Aortic Aneurysm

Joseph C. Antonio, MD, and William W. Mayo-Smith, MD

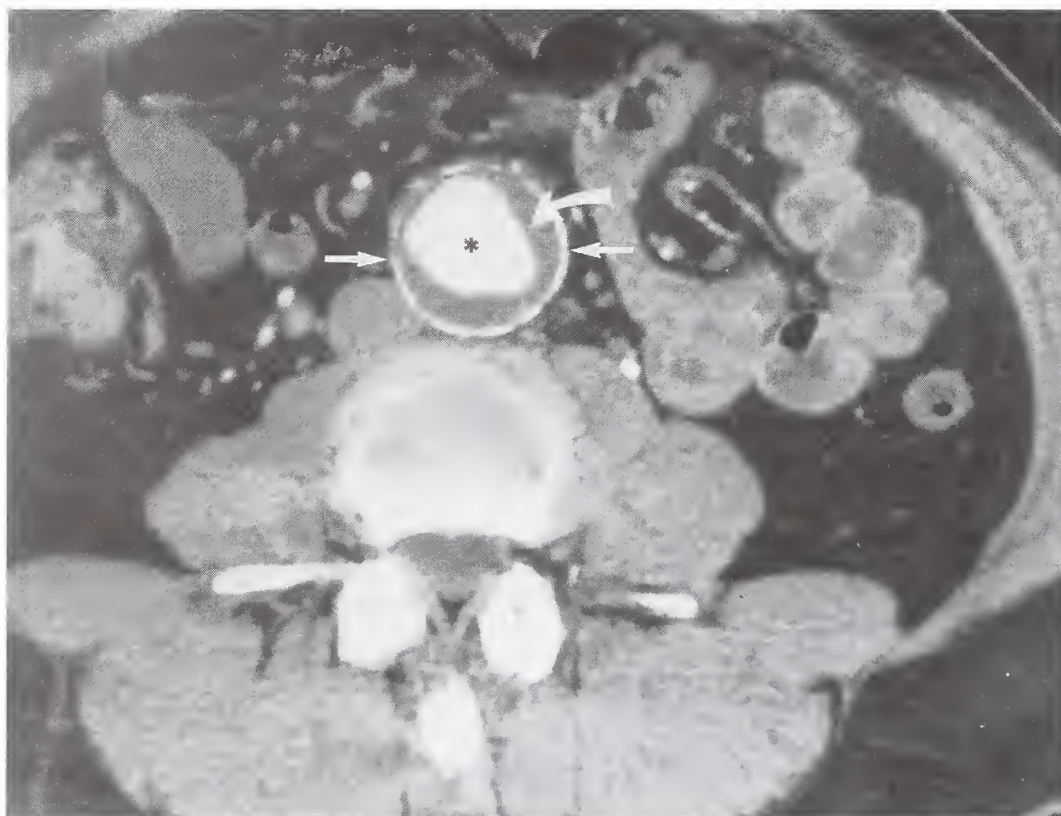


Figure 1.

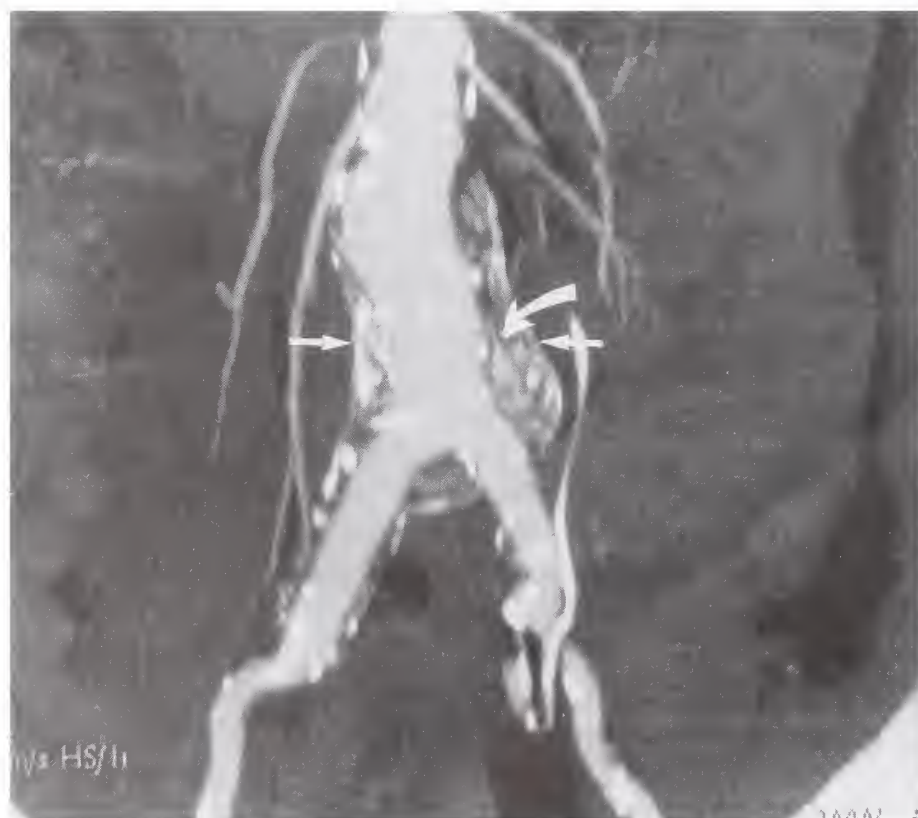


Figure 2.

Abbreviations Used:

CT computed tomography

Abdominal aortic aneurysms are a potentially life-threatening cause of catastrophic retroperitoneal hemorrhage. The larger the size of an abdominal aortic aneurysm, the more likely it is to rupture. Computed tomography (CT) can reliably detect and accurately measure the size of abdominal aortic aneurysms. Figure 1 is a contrast-enhanced CT scan which demonstrates a dilated infrarenal abdominal aortic aneurysm with a calcified wall (straight arrows), intramural thrombus (curved arrows), and a large irregular lumen (*). Figure 2 demonstrates a coronal two-dimensional projection of

the aorta created from the axial CT images. Traditionally, abdominal aortic aneurysms have been repaired by a laparotomy and surgical placement of an aortic graft. In select patients with infrarenal aortic aneurysms, endovascular repair of aortic aneurysms is now being performed by a team of interventional radiologists working with vascular surgeons. Endovascular grafts are placed into the abdominal aorta through the femoral artery using x-ray guidance. The procedure is performed percutaneously in the operating room or vascular-interventional suite and precludes the risk involved with a major laparotomy. Short-term follow-up (7.5 months) has demonstrated a low mortality and high success rate. Figure 3 is a CT scan performed after placement of an endovascular prosthesis which demonstrates the two enhancing limbs of the endovascular graft (X) and extra-graft thrombus (curved arrows). Contrast-enhanced CT is the imaging modality of choice for the diagnosis of potential candidates for endovascular graft repair of abdominal aortic

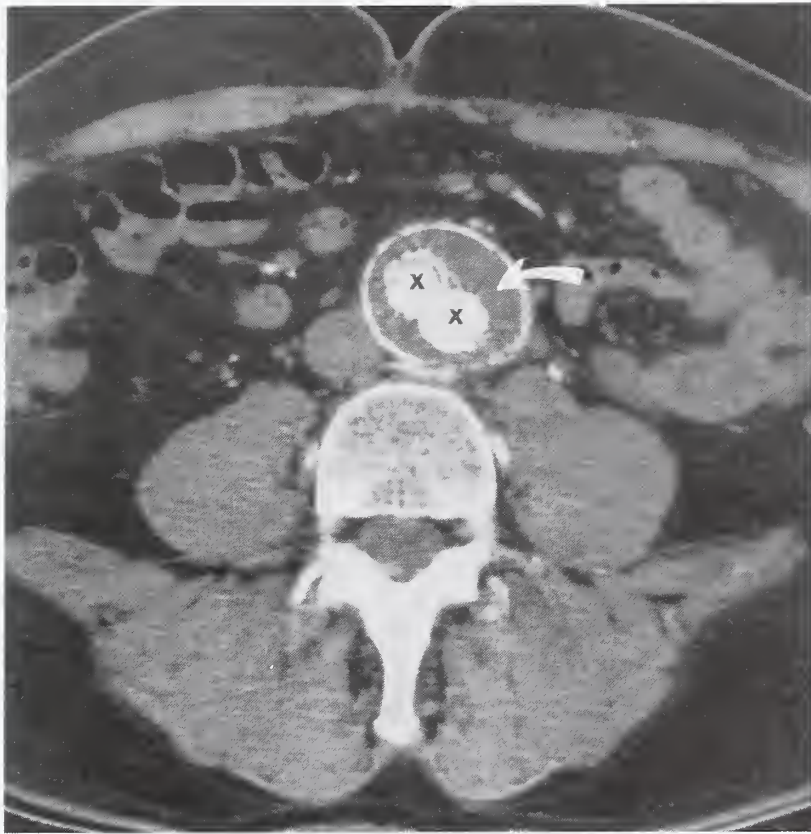


Figure 3.

aneurysms, and to follow-up patients after the graft has been placed.

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Payment Error Prevention Program: RIQP Completes Initial Pilot Projects for PEPP

Freda B. Schroeder, ScD

Rhode Island Quality Partners (RIQP), the Rhode Island Peer Review Organization (PRO), would like all providers in Rhode Island to have an up-to-date understanding of the progress of the Payment Error Prevention Program (PEPP). PEPP is designed to reduce payment errors made by Prospective Payment System (PPS) inpatient hospitals using a continuous quality improvement approach. PEPP is a national project for HCFA and hospitals' participation in PEPP is required.

During the first year of PEPP, the PROs conduct one quality improvement project on unnecessary admissions and one project on DRG miscoding. The projects selected by RIQP were based on analysis of hospital Medicare inpatient discharge data for calendar year 1998, for the high frequency and high cost DRGs. Data collection was done to identify any causes or patterns of coding and documentation in the records that would lend themselves to further analysis at the hospital level and respond to interventions for improvement.

CODING AND DOCUMENTATION: THE DRG PROJECT

Aberrant patterns in coding have been a concern to HCFA. Given the complexity of the Medicare population, variation in use of certain DRGs is expected. However, the Office of Inspector General (OIG) has noted nationwide atypically high billing patterns for some DRGs that should have been coded to a lower-weighted DRG. HCFA estimated substantial hospital overpayments attributable to incorrect DRG classifications.¹

In a study aimed at identifying coding practices related to the use of DRG 475 (Respiratory System Diagnosis with Mechanical Ventilation), RIQP selected DRG 475 for further analysis. This DRG is reserved for mechanically ventilated patients with a true respiratory system diagnosis, and carries with it a high relative weight value. The relative weight is based on the national median length of stay for this class of patients and is designed to reflect treatment costs. Reports from the OIG suggest that claims billed under DRG 475 have a significant incidence of DRG

Abbreviations Used:

CHF	congestive heart failure
DRG	diagnostic related group
HCFA	Health Care Financing Administration
OIG	Office of Inspector General
PEPP	Payment Error Prevention Program
PPS	Prospective Payment System
PRO	Peer Review Organization
RIQP	Rhode Island Quality Partners

change when the claim is reviewed for DRG validation.² OIG audits have revealed a significant proportion of DRG 475 claims for which there is insufficient documentation within the medical record to support the principal diagnosis, a key component in assigning the appropriate DRG to any Medicare claim. One factor influencing the erroneous assignment of DRG 475 is the presence of a diagnosis of pulmonary edema secondary to congestive heart failure (CHF, 428.0). As an example of how this applies: DRG 475 cannot be assigned to a claim for the treatment of respiratory failure resulting from CHF with no other qualifying respiratory diagnosis.

A total of 130 medical records from Rhode Island hospitals were selected for the project. Record abstraction revealed that 18% (n=23) were submitted for Medicare reimbursement for which insufficient documentation resulted in the incorrect assignment of the DRG. Of the 23 identified records, 22 (96 %) were DRG 475 claims. For the entire sample of DRG 475 records, 28% (n=22) were identified as not following established coding conventions. Sixteen of the identified records (73%) were identified because the principal diagnosis as billed was not the principal reason for the hospitalization. Five of the records (23%) were noted to have a significant (i.e. DRG-affecting) diagnosis or procedure coded incorrectly.

ADMISSION REVIEW: THE SHORT STAY ADMISSIONS PROJECT

In its most recent report on HCFA's Financial State-

ments, OIG provided a summary of the last four years of its review, indicating that over 70% of erroneous payments made by the Medicare Program were made where documentation was insufficient to support medical necessity of the admission.³ Short-stay inpatient admissions were found to be particularly vulnerable to questionable necessity of an inpatient stay. Generally, the documentation of admitting diagnosis and treatments were insufficient to justify complexity and intensity of care and services provided at an inpatient hospital level of care. The OIG's Work Plan for Fiscal Year 2000 has identified the question of medical necessity of short stay admissions, in the project "One Day Hospital Stays", as one of its critical projects for the current year.⁴

In accordance with our HCFA contract, RIQP developed the Short Stay Admissions Project to identify opportunities for improvement in the documentation and coding of short-stay inpatient admissions, transfers, and readmissions in Rhode Island's acute care PPS hospitals.

The findings of a review of 162 records of short-stay inpatient admissions indicated that 55% had insufficient documentation to substantiate the intensity of services provided in a hospital inpatient setting. Fifty percent (50%) of the insufficient documentation issues were associated with two DRGs: DRG 182 (Esophagitis, Gastroenteritis, and Miscellaneous Digestive Disorders) and DRG 025 (Seizure and Headache). Medicare regulation 42 CFR 482.24(c) requires providers to maintain records that contain documentation to justify diagnoses, admissions, treatments performed, and continued care.

USE OF FINDINGS

Many billing or coding errors are not intentional but the result of a complicated payment system. Many of the errors may also be clerical in nature or result from incomplete documentation. Note that the term "error" when referring to billing and coding issues is often used in the idiosyncratic manner, meaning insufficient documentation or lack of adherence to coding conventions. For example, DRG 475, while paying for equivalent services, is correct for respiratory failure but not CHF as the code is for primary and not secondary lung problems. To most physicians it seems bizarre to consider this an error because it does not relate to errors in patient care.

Educational interventions will assist in correcting these errors, and education is at the core of reducing the rate of payment errors. Documentation of facts, findings, observations, history and physical exam results, outcomes of tests and treatments need to be sufficiently organized and comprehensive as to clearly demonstrate the quality of care provided to Medicare beneficiaries. In addition, outcomes of good documentation include continuity of care among health care professionals and coordination of the patient's treatment plan.

The practice of medical record documentation can be derived from a variety of regulatory standards, including Medicare Conditions of Participation. Hospitals are encouraged to use the project findings to explore their existing coding, billing, and medical record policies and procedures. Educational interventions for hospital staff, including physicians, can focus on documentation training that will support appropriate coding and billing, be consistent with regulatory requirements, help reduce payment errors, and assist the hospital in receiving the level of reimbursement it is entitled to receive.

We are committed to working with individual providers on PEPP. If you would like to learn more, call the PEPP team for a presentation at (860) 632-6347.

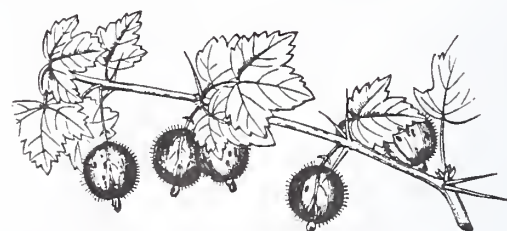
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Health by Numbers



Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Jay S. Buechner, PhD

Quality Hospital Care, What Does It Mean to Rhode Islanders?

Robert Marshall, PhD

Hospitals are one of the most utilized and expensive components of the American health care system. As efforts continue to restructure health care and control costs, the demand by employers, government, the public and others for measures of hospital quality intensifies. Many efforts seek to measure quantifiable or "technical" components of hospital quality, such as infection rates and emergency readmission.¹ Others focus on measuring the "functional" components of hospital quality, such as patient satisfaction with various services. Still others rely on external process review, such as by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or on internal quality improvement techniques, such as Total Quality Management (TQM) and Continuous Quality Improvement (CQI) techniques. No single approach satisfies every interest.

The Health Care Quality Performance Measurement and Reporting Act of 1998 (Quality Act) requires the Rhode Island Department of Health (HEALTH) to measure and report to the public on the quality performance in all licensed health facilities,

Abbreviations Used:

CQI	Continuous Quality Improvement
HEALTH	Rhode Island Department of Health
JCAHO	Joint Commission on the Accreditation of Health Organizations
TQM	Total Quality Management

beginning with hospitals. Reporting promotes quality by allowing it to be measured and improved over time. Reporting also informs consumers and health care professionals about the use of quality measures. The initial focus on hospitals caused HEALTH to examine what consumers mean by quality hospital care, what kinds of information they want about quality, how often they want it and in what format they want it.

Methods

HEALTH contracted with a marketing consulting firm to conduct focus groups with health care consumers, physicians, hospital quality assurance managers and chiefs of hospital patient care.² Follow-up interviews took place individually with health plan medical directors, hospital CEOs, and employer benefits managers. Researchers used this information to design survey questions for consumers about quality hospital care.

The HEALTH consultant also surveyed 454 adult Rhode Islanders using a random-digit-dial telephone survey technique during June 7-21, 1999.² Researchers stratified the sample by age and other characteristics. The response rate was 30%. The results produced a margin of error at $\pm 4.6\%$ at the mid-range of the 95% confidence level. The small percent of respondents from minority groups (7%) did not permit useful analysis by minority status.

Results

Respondents to the consumer survey reported clear opinions about quality of care in the United States and Rhode Island. Most (53%) rated the overall quality of care provided by hospitals in Rhode Island as "good" or "excellent." Nineteen percent said that it had "improved" over the last five years; more (28%) said it had "gotten worse"; most (38%) said it had "stayed about the same." More than half (52%) of all respondents thought that the quality of care provided by individual hospitals in Rhode Island was "about the same" across hospitals.

The survey also asked consumers whether they thought of quality hospital care as "good outcomes" or as "being treated well." Responses favored "being treated well" by a two to one margin. (Figure 1) This finding persisted among all but high in-

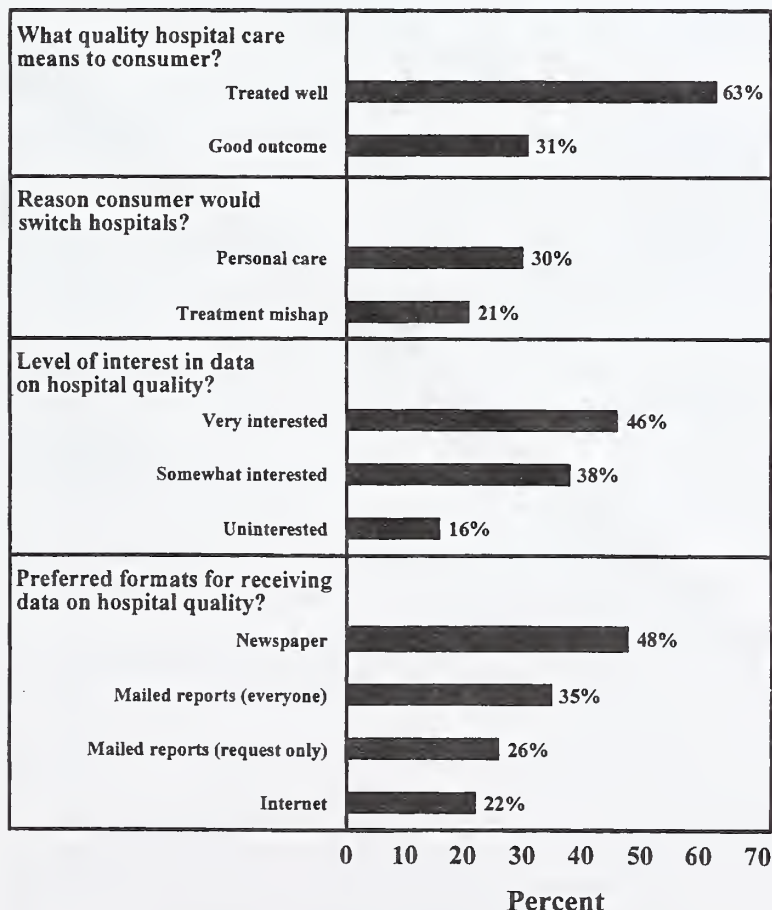


Figure 1. Consumer Opinions on Hospital Quality Information, Rhode Island, 1999.

come (>\$75,000) and high education (college graduate) groups, who emphasized "successful outcomes." Most respondents (51%) think of hospital administrators, not their doctors (25%), as responsible for the quality of care that hospitals provide.

The survey also explored the "actionability" of information on hospital quality - whether or not respondents would use it to make different decisions about health care. Only 21% of consumers would switch hospitals after learning about a "reatment mishap," but 30% would switch after hearing "negative things about personal care" in a hospital. (Figure 1) Most respondents currently get information on hospital quality from their doctors (39%) or by word-of-mouth (40%), but many (84%) also expressed interest in getting objective information in other ways. Preferred formats included newspaper reports (48%) or printed reports mailed to all households (35%). College graduates (41%) preferred availability on the Internet. Most interested consumers (88%) want the information updated frequently, at least annually.

Discussion

This research points out some of the key challenges of promoting quality hospital care by measuring and reporting systematically-collected data. Consumers hold clear perspectives on quality hospital care but not always the same ones as health professionals. Consumers emphasize the functional aspects of quality hospital care, such as satisfaction or being treated well; health professionals tend to focus on technical aspects such as treatment outcomes. Consumers remain largely unaware of sophisticated and often expensive hospital methods and procedures to ensure overall quality. Even though consumers say they hold hospitals responsible for the care they provide, for most

that care is ancillary to diagnosis and treatment provided by their own personal physician.

Evidence exists that the public does not understand and is not yet prepared to act on information on hospital quality. Consumers typically assume the "sick role," giving authority to physicians and other providers to make health care decisions for them. They also rely heavily on their physicians for direction and on word of mouth recommendations in evaluating hospitals. But consumers remain quite interested in information about hospital quality. In addition to producing comparative data, health and hospital officials need to provide a strong consumer education program to ensure the understanding and use of both technical and functional quality information.

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Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Underlying Cause of Death	Reporting Period			
	Sept. 1999	12 Months Ending with Sept. 1999		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	232	2,974	300.9	3,865.5
Malignant Neoplasms	199	2,504	253.3	6,919.0
Cerebrovascular Diseases	32	553	55.9	586.5
Injuries (Accident/Suicide/Homicide)	42	376	38.0	6,820.0
COPD	27	511	51.7	350.0

Vital Events	Reporting Period		
	March 2000	12 Months Ending with March 2000	
	Number	Number	Rates
Live Births	888	12,820	13.0*
Deaths	834	9,970	10.1*
Infant Deaths	(6)	(95)	7.4#
Neonatal deaths	(4)	(79)	6.2#
Marriages	347	7,824	7.9*
Divorces	210	2,683	2.7*
Induced Terminations	510	5,047	393.7#
Spontaneous Fetal Deaths	69	1,049	81.8#
Under 20 weeks gestation	(62)	(978)	76.3#
20+ weeks gestation	(7)	(71)	5.5#

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

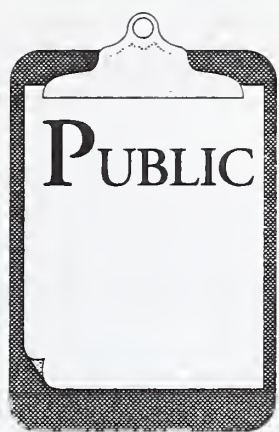
(b) Rates per 100,000 estimated population of 988,480

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population

Rates per 1,000 live births



Adult Vaccinations: 2000-2001 Flu Season Update

Thomas E. Bertrand, MPH

Rhode Island can be proud of its childhood vaccination rates; in 1999 Rhode Island ranked number one in the United States for childhood immunizations; 90.4% of age-eligible children were up-to-date on their childhood vaccinations in that year.¹

However, Rhode Island adults ages 65 and over have not fared as well as their younger counterparts. Although immunization rates have been on the rise in this population, the current rates of immunization (73.7% for influenza and 54.7% for pneumococcal disease²) fall far below the Healthy People 2010 goal of 90%. These low rates of vaccination translate into substantial mortality and morbidity. In 1996, for example, there were 6,814 hospitalizations and 310 deaths associated with influenza and pneumococcal disease in Rhode Island. At a time when safe and effective vaccines are readily available, these statistics underscore the need to improve the delivery and acceptance of recommended vaccines.

2000-2001 FLU SEASON UPDATE

The challenges of improving influenza immunization rates may be compounded during the 2000-2001 influenza season because influenza vaccine may be in short supply. According to the Centers for Disease Control and Prevention (CDC), lower than anticipated production yields for this year's influenza A(H3N2) vaccine component and other manufacturing problems are expected to cause a significant delay in the distribution of influenza vaccine and may result in fewer total doses of vaccine for distribution than last year.³

The CDC and the Advisory Committee on Immunization Practices (ACIP) have issued the following adjunct influenza recommendations for the 2000-2001 influenza season:

- Organized influenza vaccination campaigns should be delayed until November (Note: this recommendation is being implemented by the Ocean State Adult Immunization Coalition).
- Influenza vaccination of individuals at high risk for complications from influenza and their close contacts during regular health care visits should proceed routinely.
- Provider-specific contingency plans for an influenza vaccine shortage should be developed.

Ironically, CDC's announcement of potential vaccine shipment delays and fewer doses falls on the heels of the ACIP's recent recommendation to broaden influenza vaccine administration to all persons between 50 and 64 years of age, reflecting an effort to increase vaccination coverage of persons with high-risk conditions. In the event of a vaccine shortage, CDC recommends having contingency plans for vaccinating persons with high-risk conditions.

PRIMARY CARE

Primary care providers play a key role in ensuring that their adult patients receive recommended vaccines. In 1999, A National Medical Association panel of experts concluded that the major barrier to adult immunizations was a general lack of awareness because the provider failed to recommend it.⁴ In order to heighten awareness in physician offices and improve vaccination rates, the following materials are available in bulk (free of charge) during September and October from the Ocean State Adult Immunization Coalition. [Contact: Annemarie Beardsworth, phone: (401) 222-2577]:

- Wall posters (English/Spanish)
- Vaccine Information Sheets (influenza, pneumococcal, various languages)

Abbreviations Used:

ACIP	Advisory Committee on Immunization Practices
CDC	Centers for Disease Control and Prevention

- Wallet-size personal immunization records
- Immunization Flyers (English, Spanish, Portuguese, Cambodian, Loatian)
- Immunization Pins/Buttons for health care professionals
- TB and Immunization Records for patient medical files

CONCLUSION

If Rhode Island is going to reach its Healthy People 2010 goal for adult immunization (90% coverage), efforts must begin now. "Getting your shots" should be as common a goal for older adults as it is for children.

FOR MORE INFORMATION

Visit the CDC's website on influenza at: <http://www.cdc.gov>, or the National Foundation for Infectious Diseases's website at <http://www.nfid.org>.

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THE RHODE ISLAND MEDICAL JOURNAL

The Official Organ of the Rhode Island Medical Society
Issued Monthly under the direction of the Publications Committee

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NUMBER 1

PROVIDENCE, R.I., JANUARY, 1917

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NINETY YEARS AGO

❧ [SEPTEMBER, 1910] ❧

This issue announced the regular publication, within the Journal, of the Transactions of the Rhode Island Medical Society.

In "A New Home for the Rhode Island Medical Society," this issue also announced the purchase of 6000 square feet at the corner of Francis and Hayes Street, "facing the extensive grounds of the State Capitol and bounded on the South by the State Normal School and with the possibilities of further adornment between it and Union Station. When the freight yard is removed, as it ultimately will be, the view will be unexcelled."

George S. Matthews, MD, in "Some Manifestations of the Angio-Neurotic Group of Diseases," described four cases. A 41 year-old foreman in the city Sewer Department, admitted to Rhode Island Hospital, began with a "history of attacks of pain and lameness in ankles, calves, knees, hip. Purpuric spots on knees, calves, thigh. Colicky pains in abdomen." He progressed: "Some edema of feet...Herpes. Nephritis. Endocarditis. Death." The other three patients recovered, even though Dr. Matthews prescribed no specific treatment, other than "rest in bed during the attack with properly regulated feeding.....nitroglycerine, lactate of calcium, gelatin, ice...for the hemorrhage."

F.C. Clark, MD, in "The Dispensing Druggist" discussed the division of labor in the prescribing, mixing, and dispensing of medications - arguing that pharmacists should not prescribe medications. In this era, before the "standardization" of drugs, some physicians dispensed their own medications (mostly rural practices - larger practices could not afford the time or space); manufacturing chemists ("druggists") mixed the medications; and pharmacists ("retailers") dispensed them - though the lines were not clear. F.C. Clark conceded the financial pressures on pharmacists to prescribe, given the onslaught of "manufactured" pills. "Tons on tons of pills and compounds and compressed tablets, with some of them of the most unexceptional character, have been put upon the market at prices that would bring many a retailer to the verge of starvation..."

FIFTY YEARS AGO

❧ [SEPTEMBER, 1950] ❧

Samuel Spadea, MD, in "Osteoid Osteoma of the Astragalus," reported on the 13th case of this lesion in the literature (since Jaffe first reported the lesion in 1935). In August 1945 the 25 year-old male patient had fallen and turned his right ankle during an air raid in the Philippine Islands. After a few days, the pain and swelling subsided, followed by bouts

of pain after long walks or standing for several hours. By February 1947 he was in more pain, particularly at night, and was limping. He had no fever or other symptoms. After x-ray, surgeons removed an area "the size of a 10-cent piece."

Edward Damaryjian, MD, in "Sympathetic Nerve Block," described this "comparatively new therapeutic and diagnostic procedure," reviewing 9 cases (of sympathetic causalgia or dystrophy, phantom limb, herpes roster, hyperhidrosis, thrombophlebitis, severe trauma). The author urged that "patients...be given a fair trial of sympathetic blocks before surgery is considered."

An Editorial on Nuclear Therapy predicted that it "...will rank equally with our recent conquest of pyogenic agents through antibiotics."

TWENTY FIVE YEARS AGO

❧ [SEPTEMBER, 1975] ❧

This issue focused on Alcoholism and Medical Education. Levi C. Adams and Stanley M. Aronson, MD, introduced a January 31-February 1 Conference on Teaching of Alcoholism in United States Medical Schools, sponsored by Brown University School of Medicine. Malcolm Todd, MD, immediate past president, AMA, gave the keynote address: "How Future Physicians Must See The Alcoholic" ("Alcoholism is essentially a medical rather than a moral problem.") William G.A. Bosina, MD, Director, Division of Alcoholism and Drug Abuse, University of Maryland Hospital, spoke on Alcoholism in Undergraduate Medical Education; Kenneth H. Williams, MD, Assistant Professor of Psychiatry and Medicine, University of Pittsburgh, spoke on Alcoholism in Graduate Medical Education. An Editorial noted the depth of the problem ("at least 1 of every 17 Rhode Islanders is an alcoholic"); the dearth of resources ("[there is]...not a single detoxification center within the city of Providence. The general hospitals usually refuse to accept alcoholics for treatment of their alcoholism, but...refer such cases to the State Institute of Mental Health at the Rhode Island Medical Center"); the existing services (61 Alcoholics Anonymous groups in the state); and the prognosis for improvement (Butler's application for \$4 million in federal aid to provide a treatment program, Mayor Cianci's request for a state grant to develop a network of treatment facilities in Providence).

In "A Message from the Dean," David S. Greer, Associate Dean of Medical Affairs, described "Family Practice Education - A Progress Report." He noted, "Education in family medicine has made its debut in Rhode Island, with 8 residents in the model Family Care Center on the grounds of Memorial Hospital." "Residents...are assigned their own patients and families, whom they will care for throughout the 3-year training period; in this way, they begin functioning as family physicians immediately after graduation from medical school." The author expected a "significant number" of residents to practice in Rhode Island, taking their patients with them.



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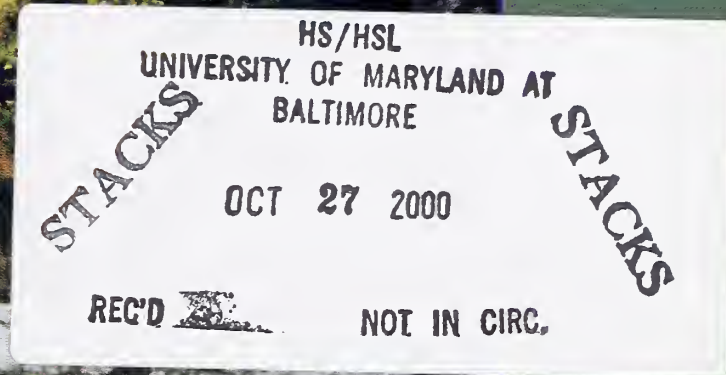


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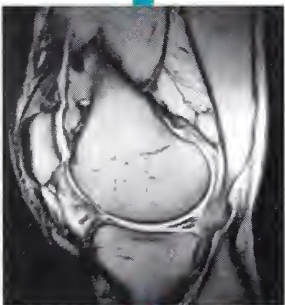
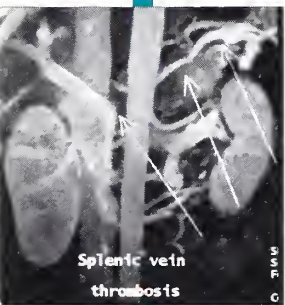
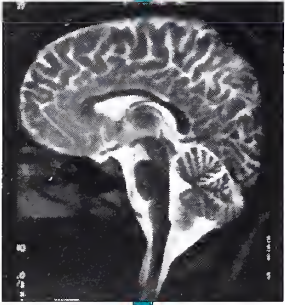


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COMMENTARIES

Best Doctors

Every few years, the *Rhode Island Monthly* lists the "Best Doctors in Rhode Island." These names are chosen via a questionnaire mailed to all Rhode Island physicians, asking them to select the one doctor in each discipline they think is the best.

There are certain obvious problems with this and certain not-so-obvious problems. The clearest problem is the sheer discrepancy in the odds of being chosen as one of the best internists, pediatricians, or psychiatrists, where the total number of doctors in the discipline is large, versus being chosen for neurology, radiation oncology, or some other relatively small specialty.

Another obvious problem lies in the nature of specialty and subspecialty care. The "best" orthopedist for a shoulder problem is probably not the best one for a complicated hip problem. The world's best plastic surgeon for congenital skull deformities may be only average at cosmetic surgery. This makes it difficult to define what "best" means in terms of technical expertise. Is Dr. X, the left shoulder specialist, better than Dr. Y, the right shoulder specialist, because Dr. X publishes more papers, sees more patients, takes on more difficult cases, gives more professional talks, or has a national rather than local reputation? What if Dr. Y excels in some of these areas and Dr. X in the others? Do "people skills" count? I constantly wonder at some colleagues who warn their patients before referring them to a particular consultant, "He's rude and he's crude, so don't listen to what he says. He's very competent. He's great technically. He'll report to me and then we'll decide what to do". Have my colleagues actually voted for this particular physician? I don't know. He's not been on any list that I can recall, but it raises the question of what we mean by best. Is he the best in his specialty in this re-

gion? I don't even think the referring doctors think that. They do think he's the best in their hospital, though, and he'll see patients in a timely manner and he'll communicate with the doctors at each decision point, just not so well with the patients.

And one observation I've made over the years is that names often appear and disappear in conjunction with changes in practice patterns. A specialist joins a large multi-specialty group practice and makes the list. She leaves the group, goes into solo practice, and drops off the list. It is interesting how important referral patterns are for professional standing in the community. Which isn't to imply that whom one practices with is more important than how one practices, but it is a factor that goes into the determination.

I don't think that individual popularity within the constellation of Rhode Island physicians is an important determinant of ranking. It certainly counts less than the ability of the doctor to relate to the patient. I believe that many of us have voted for doctors we barely

know based on our colleagues' experience, our own patients' comments, and the quality of the office notes and patient care we've observed. Politics is therefore not involved.

How patients interpret these lists is unclear to me. Certainly those whose doctors' names are on the list feel reassured that they're "in good hands," possibly "the best," but what does it do to the bulk of patients whose doctors' names are not on the list? Does it undermine their confidence? Do they think they're getting less than the best care? Do they switch? I don't think anyone knows and there is probably no way to find out.

So, what does it mean to be voted as on the best? It is certainly an honor. To be considered so highly by one's colleagues reflects a level of accomplishment we all crave at some level. But it is equally certain that it doesn't mean one is the best or that those not on the list are worse than the best. In medical school, I was told once that the greatest mark of collegial respect was to be brought a physician's family member for evaluation. Whether I internalized this because I was younger and more impressionable or whether it is a more tangible token of confidence, it still strikes me as the highest sign of recognition, more than any list or award.

— Joseph H. Friedman, MD



The Specter of River Blindness

Africa is home to about 850 million people. It is also the site of the world's most intense concentration of infectious disease. Tropical heat, vast insect populations, relative paucity of medical resources, widespread poverty and periodic social unrest conspire to enhance the incidence of parasitic and communicable disease. Many of the burdensome diseases of humanity such as malaria, sleeping sickness and schistosomiasis, are concentrated in Africa; and now the spread of AIDS devastates many of the developing nations of this continent. Indeed, of the 33.6 million known cases of HIV/AIDS infection worldwide, 23.3 million are now centered in Africa.

Yet Africa, with all of its infectious morbidity, is also the site of many public health triumphs. East Africa, in 1977, witnessed the final eradication of smallpox and the globe has since been free of this scourge. And in west Africa another organized campaign is currently leading, region by region, to the extinction of a terrible parasitic disorder which has blinded vast numbers of Africa's farmers, a disease called onchocerciasis.

The conquest of onchocerciasis had its modest beginnings in 1874 when the disease was demonstrated to be caused by a parasitic worm. John O'Neill, a British naval surgeon, was temporarily stationed in the west African colony of Gold Coast [now the independent nation of Ghana.] He became interested in a widespread skin disease of rural agricultural workers, a disease locally called craw-craw. The disease, which looked like scabies, caused an intense itching. The affected skin showed a confluent rash with superimposed, small reddish papules. O'Neill punctured the surface of one of these papules and squeezed out a drop of milky fluid which, under the microscope, contained squirming worm-like creatures called filaria.

O'Neill noted in passing that many of those afflicted with this skin disorder were also burdened with larger, egg-sized subcutaneous lumps. Other physicians, exploring the composition of these larger masses, found their interior to be filled with clusters of living worms, some as long as 20 inches. The parasite, a heretofore unidentified nematode, was eventually called *Onchocerca volvulus* and the disease, onchocerciasis.

Many onchocerciasis victims, in addition, were disabled by an eye disease which began as an irritation caused by the microscopic filaria infiltrating the coverings of the eyeball. And when some of these invasive larvae died, the body reacted with local scarring. This tissue response caused the cornea to lose its transparency, leading ultimately to blindness. Experienced physicians could often identify, from afar, those with eye involvement since they tended to avoid bright sunlight by constantly shielding their irritated eyes.

Surveys of the rural population of the nations of west

Abbreviations Used:

AIDS	acquired immune deficiency syndrome
HIV	human immunodeficiency virus
OCP	Onchocerciasis Control Programme
WHO	World Health Organization

Africa confirmed that about one-third of field workers suffered from the skin manifestations of onchocerciasis and one-fifth showed mild to severe eye impairment.

Preventive medicine doesn't work if one doesn't know what to prevent. The obvious first question to explore, then, is the pathway by which the worm enters the victim's body. Water and food contamination had been ruled out. An insect vector capable of transmitting the microscopic forms of the parasite was then sought. By the early decades of the 20th Century the full biological cycle of the parasite was finally clarified: The female African black fly [prophetically named *Simulium damnosum*], a voracious biter, was finally shown to be the carrier of the microscopic form of the worm. The fly bites an infected human; and within a week the parasites have infiltrated the fly's biting apparatus; and when the black fly next bites a human it will inject the larval forms into its new victim. Some of these larval forms will then mature into adult worms which will mate within the victim's body [forming the large lumps under the skin] and the female worm will then liberate millions of tiny worms which induce the skin disease and the eye impairment.

The black fly is an idiosyncratic insect. In contrast to most species of fly, it lays its eggs solely in swiftly coursing streams, the eggs adhering to subsurface gravel until they mature. Adult black flies generally confine their activities to within a few miles of the stream; and the great majority of cases of onchocerciasis are therefore contracted by men working in farmland adjacent to streams or rivers [hence the common name for the disease, River Blindness.]

Onchocerciasis is also found in some central American nations such as Guatemala. Epidemiologists believe that the parasite was passively transferred to the New World in the 17th Century by African slaves.

By the 1960s, many central and west African nations were confronting immense economic losses when much of their most productive farmland became inaccessible because of the swarms of onchocerca-carrying black flies. The World Bank then elected to fund a massive transnational campaign to suppress and eventually eradicate onchocerciasis from sub-Saharan Africa. It chose the World Health Organization (WHO) to supervise this ambitious undertaking called the Onchocerciasis Control Programme (OCP)

The OCP consisted of three interacting components: [1] Attack the black fly vector at its sites of propagation by adding biodegradable insecticide to the headwaters of thou-

sands of African streams and rivers. [2] Treat all of those currently suffering from onchocerciasis. By 1978, the Merck pharmaceutical laboratories had isolated an effective antifilarial antibiotic, called ivermectin, which was extracted from a species of fungus. Merck agreed to provide the WHO with unlimited supplies of the agent free of charge. By 1992, over 10 million Africans had been treated successfully. And [3] Modify behavior of the field workers by encouraging them to wear protective clothing and use insect-repellents.

By 1995 the OCP had virtually eliminated onchocerciasis from eleven west African nations at a cost of about 180 million dollars. The program has prevented at least 500,000 cases of blindness and has liberated about 25 million hectares of rich farmland, land that had previously been

unavailable because of rampant onchocerciasis. The increased agricultural productivity rates alone more than offset the costs of parasite eradication.

Onchocerciasis still persists in isolated pockets both in central Africa and Central America. WHO has established the year 2006 as the time when it confidently expects to announce global eradication of onchocerciasis.

First it was smallpox; now, within a decade, poliomyelitis, measles and onchocerciasis will join the select list of infectious diseases eradicated by men and women working creatively and collectively to make the globe a more congenial place to live. Is not the giving of sight to half a million persons a miracle worthy of celebration?

— Stanley M. Aronson, MD

Abstracts: American College of Physicians – American Society of Internal Medicine Annual Meeting

Fred J. Schiffman, MD, FACP

INTRODUCTION

This year the ACP-ASIM featured medical resident presentations once again as the centerpiece for our Annual Meeting, held on Friday, April 28, 2000, at the Radisson Airport Hotel in Warwick, Rhode Island.

There were 67 posters presented by house officers from Brown University and Boston University teaching hospitals and 7 oral presentations - 3 given to the assembled group in the morning and 4 in the afternoon.

Topics for the oral presentations were of varied and extraordinary interest to the presenters and the assembled group. Topics ranged from the highly molecular such as the paper, "p53 Mutations do not predict response to paclitaxel as a single agent for metastatic non-small cell lung cancer," presented by Dr. Alice Fan, to the highly clinical such as the paper, "Infliximab efficacy in Crohn's disease one year after its release," presented by Dr. Thomas Vallone.

Following each presentation there was spirited questioning of presenters and lively audience discussion. The participation by our medical residents and their faculty members is a fine ex-

ample of the scholarly mission of the ACP-ASIM and has become a tradition for medical residents and faculty in Rhode Island and for members of the ACP-ASIM each year.

Fred J. Schiffman, MD, FACP, is Professor of Medicine at Brown University School of Medicine, and Governor, ACP-ASIM, Rhode Island Chapter.

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Abbreviations Used:

AMI	acute myocardial infarction
CABG	coronary artery bypass graft
CCU	coronary care unit
CT	computed tomography
HALK	hydroxyalkenals
HR	hypoxomic reperfusion
MDA	malonaldehyde
MRI	magnetic resonance imaging
NSCLC	non-small cell lung cancer
SCLC	small cell lung cancer
SSCP	single-strand conformation polymorphism
TNF-a	tumor necrosis factor-a



Are Statins Used Optimally After Acute Myocardial Infarction?

Jeffrey P. Steinhoff, MD, William Nicholson, MD, Ara Sadaniantz, MD

THE MIRIAM HOSPITAL/RHODE ISLAND HOSPITAL

Multiple placebo-controlled secondary prevention trials have demonstrated the benefit of HMG-CoA Reductase Inhibitors (Statins) in reducing the cardiovascular morbidity and mortality. To assess their utilization, we evaluated patients with acute myocardial infarction (AMI) admitted to the Miriam Hospital CCU from April 1998-April 1999.

The CCU database is prospectively compiled with demographic and diagnostic data. We selected 190 consecutive patients with clinical, EKG, and biochemical evidence of AMI. Exclusion criteria were transfer to another institution or in-hospital death. Patients discharged with and without statins were compared using the Student's *t*-test for continuous variables and Kruskal-Wallis test for discrete variables. Multivariate analysis was performed to identify variables (demographics, baseline medications, risk factors and treatment modalities) associated with statin use.

Only 54% of the patients were discharged on statins. The baseline characteristics such as age, sex, risk factors, extent of AMI, and type of AMI (Q-wave vs. non-Q-wave) were similar between the groups. Patients discharged on statins compared to those who were not, were more likely

to be admitted on a statin (45% vs. 6%, $p=0.001$), treated with IIB/IIIA inhibitors (50% vs. 28%, $p=0.003$, and have serum lipid evaluated on admission (44% vs. 29%, $p=0.04$). Lipid profiles were evaluated in 35% of all patients. Among patients treated with statins before admission ($n=49$), 90% were continued at discharge. Among those who were not on statins at admission, 37% were discharged on statins. Multivariate analysis indicated that lipid evaluation on admission ($p=0.02$), treatment with IIB/IIIA inhibitors ($p=0.03$), and statin treatment on admission ($p=0.001$) were the only variables associated with being discharged on a statin. In this cohort 27 patients underwent CABG, of which 33% were discharged on statins ($p=0.02$).

Our data show that many patients who would potentially benefit from statin use are not treated upon discharge. Further studies are needed to demonstrate whether this trend holds true on an outpatient basis. Lipid profile inclusion as part of the admission protocol may improve the use of statins.

The Limitations of Bone Scan vs. MRI for Bone Metastases

Hussam Hamdalla, MD, Shyam Kottlil, MD, Robert Fram, MD

MEMORIAL HOSPITAL OF RI

Small cell lung cancer (SCLC) occurs almost exclusively in smokers and represents 15% of all lung cancers. SCLC is characterized by rapid tumor doubling time, high growth fraction, and the ability to metastasize early. The important prognostic factors include performance status, body weight and tumor-related factors involving the extent of the disease. Bone scans offer a quick and inexpensive survey of all bones, and are quite sensitive, although not specific, in detection of metastatic disease involving the cortical bone. Of all the patients with normal findings on bone scan, 6% present with metastases within one year. MRI has been advocated by some in the detection of bone marrow involvement, particularly in SCLC.

A 60 year-old man presented with hematuria and right knee pain. He complained of a history of weight loss, anorexia and night sweats. He had a history of smoking 3-4 cigars/day for 30 years. He had not seen a physician for the past four years. His examination was remarkable for bilateral inguinal and axillary lymphadenopathy. A chest-abdomen-pelvis CT scan showed a left upper lobe mass with multi-organ metastases, including liver, adrenals, kidneys, prostate and soft tissue. Biopsy of a subcutaneous

nodule showed small cell carcinoma. Bone scan was positive for metastases to the humeri and both femurs and uptake was not increased in the spine. Because of back pain and abnormal neurologic examination, screening MRI of the spine was done. It demonstrated extensive vertebral involvement by tumor and epidural metastases at T9 and L3-4.

This case emphasizes the limitations of the bone scan and the sensitivity of the MRI in a patient with extensive bony involvement by small cell carcinoma. Extensive involvement of the bone by tumor may not be associated with increased osteoblastic activity, thus resulting in a negative bone scan. An MRI of the spine should be considered in patients with advanced metastases and neurological signs despite a negative bone scan.

p53 Mutations Do Not Predict Response to Paclitaxel as a Single Agent for Metastatic Non Small Cell Lung Cancer

Alice Fan, MD, Thomas King, MD, PhD, Wallace Akerley, MD, Kathleen Walsh, Sham Mangray, MD, Meihsu Chen, MS, Howard Safran, MD

THE MIRIAM HOSPITAL/RHODE ISLAND HOSPITAL

Wild-type p53 protein is required to induce apoptosis in response to a wide variety of chemotherapeutic agents and ionizing radiation. p53 mutations have been associated with resistance to cisplatin in non-small cell lung cancer (NSCLC). In vitro data and animal studies suggest that paclitaxel may have a unique ability to activate tumor cell apoptosis in the absence of wild-type p53 function. Response to paclitaxel and concurrent radiation is not affected by p53 mutations in NSCLC. We sought to determine whether p53 mutations affect response to paclitaxel alone in patients with metastatic NSCLC.

Twenty-five patients with metastatic NSCLC who participated in Brown University Oncology Group protocols using single agent weekly paclitaxel had tumor tissue that was adequate for analysis. Tissue was evaluated for p53 gene mutations by single-strand conformation polymorphism (SSCP) analysis. Mutations were confirmed by

direct sequencing of altered mobility products.

Mutations in p53 were found in 8/25 patients (32%). In seven cases, a point mutation predicted an alteration in amino acid sequence. The eighth was a frameshift mutation. Response rates were compared by Fisher's exact test (two-sided). The response rates of 75% for patients with tumors with p53 mutations, and 47% for patients with wild-type p53, do not differ significantly ($p=0.21$). The one-year survival rates for patients with and without p53 mutations after treatment with paclitaxel were 63% (95% CI: 31%-100%) and 53% (95% CI: 33%-86%), respectively.

The presence of p53 mutations do not adversely affect response to paclitaxel as a single agent in metastatic NSCLC. These results provide clinical support for in vitro observations that paclitaxel can bypass mutant p53 and lead to tumor cell death by alternative pathway(s). Paclitaxel should be considered as a component of treatment for patients with metastatic NSCLC with p53 mutations.

Infliximab Efficacy in Crohn's Disease One Year After Its Release

Thomas M. Vallone, DO, and Alan Epstein, MD

ROGER WILLIAMS MEDICAL CENTER

Therapy for active Crohn's disease has changed little over the past 30 years. Tumor necrosis factor- α (TNF- α) is thought to be an integral cytokine in the inflammatory process present in the intestinal wall of Crohn's patients. Recent studies have reported clinical efficacy of infliximab, a genetically engineered antibody to human TNF- α , in the treatment of moderate to severe Crohn's Disease and fistulizing disease. We report the effectiveness of infliximab for patients with active Crohn's ileitis, ileocolitis, colitis or fistula disease and its role in minimizing steroid use.

We reviewed the medical records of eight patients with Crohn's Disease treated for 1-3 sessions with infliximab therapy. A session consisted of either a single 5mg/kg infusion or three 5mg/kg infusions at 0 weeks, 2 weeks and 6 weeks (fistula regimen). Responses were graded as complete, partial or no response based on clinical, endoscopic, or histologic findings at or before 6 weeks following each session.

After 9 treatment sessions for Crohn's ileitis, colitis, or both, there were 5 partial responses and 4 complete responses. In 5 treatment sessions for perineal fistula disease, there were 3 partial responses, 1 complete response, and 1 no response. Nine of 13 successful sessions (i.e., partial or complete response) were achieved without the use of steroids. In 3 of the 4 other successes, steroid treatment was tapered off at 3 weeks, 3 months, and 4 months respectively. Interestingly, not one patient needed a hospital inpatient admission for Crohn's symptoms after initiation of infliximab therapy. One day following the initial infusion, one patient had muscle weakness which was not treatment-limiting. No other adverse effects were reported.

Infliximab therapy has success in the treatment of Crohn's ileitis and/or colitis, and fistula disease and reduces steroid use.

Analysis of Clinical Outcome After Treatment of Chronic Infection with Hepatitis C Virus

Dimitriy Leongardt, MD, Alan Epstein, MD

ROGER WILLIAMS MEDICAL CENTER

Hepatitis C is the most common cause of chronic viral hepatitis in the United States, with almost 4,000,000 people already infected and 3,000 new cases per year. Currently Hepatitis C is responsible for 8,000 to 10,000 deaths annually, and without effective intervention that number is expected to triple in the next 10 to 20 years. It is also the most common indication for liver transplantation, accounting for 30% of all cases.

To compare results of treatment of chronic infection with Hepatitis C virus with single agent and combination therapy protocols. 194 cases of hepatitis C infection were reviewed. 77 patients (40%) did not receive any treatment, in most cases secondary to concomitant substance abuse and psychiatric disorders. 117 patients (50%) have been started on various treatment protocols. Of these 117 patients, 64 completed treatment, 26 currently continue, and 27 stopped treatment. 36 persons completed treatment with interferon alone, 5 (14%) successfully and 31 (86%) failed treatment. Successful outcome was defined as normal liver function tests and absence of hepatitis C RNA in peripheral blood at least 6 months after treatment has been completed. 19 patients who did not receive treat-

ment in the past (interferon-naive) completed combination treatment with interferon alpha and ribavirin; 19 (90%) successfully and 2 (10%) failed. Of these 17 patients, 13 (76%) participated in a clinical trial, which evaluated higher interferon dosing. 10 patients who were treated in the past with interferon alone (interferon-relapsed) completed combination treatment - 4 (20%) successfully and 16 (80%) failed.

Until recently interferon alpha was the only therapy available for patients with chronic Hepatitis C. However, only 15 to 20% of patients achieve sustained response to interferon therapy. Combination treatment of chronic Hepatitis C infection with interferon alpha and ribavirin is more effective in terms of clinical outcome, with more than 40% response rate. New antiviral agents, such as sustained-release forms of interferon as well as inhibitors of HCV-specific protease and RNA polymerase will likely be needed for management of non-responders, and will be developed in the next decade. It is likely that the management of chronic Hepatitis C in the future will involve use of combination of several drugs and resemble that of antiviral therapy of acquired immunodeficiency syndrome.

The Effect of Hypoxemic Reperfusion on Cerebral Protection after a Severe Ischemic Brain Insult

Dimitrios I. Karpaliotis, MD, Emmanuel E. Douzinas, MD, Ilias Andrianakis, MD, Marinos T. Pitaridis, MD, Epaminondas M. Kypriades, MD, Klea Katsouyannin, DMed Sc, Dimitrios Sfyras, MD, Yiannis Gratsias, MSc, Apostolos Papalois, PhD, Charis Roussos, MD, PhD

THE MIRIAM HOSPITAL/RHODE ISLAND HOSPITAL; UNIVERSITY OF ATHENS MEDICAL SCHOOL; EXPERIMENTAL LABORATORY OF ELPEN-PHARMACEUTICAL COMPANY

Reactive oxygen species contribute to membrane lipid peroxidation and neuronal death and have been implicated in the injury caused in various models of cerebral ischemia and reperfusion. We tested if hypoxemic reperfusion (HR) after cerebral ischemia would improve neurologic recovery.

Two groups of piglets (n=11 in each group) were submitted to a model of a 10-minute partial cerebral and systemic ischemia to compare the effect of hypoxemic reperfusion (group HR) to the classical hyperoxemic control (group C). A third group not subjected to ischemia served as control to the group control (n=6, group CC) but was submitted to hyperoxygenation at the respective period of reperfusion. The outcome was evaluated by means

of neurologic assessment and the extent of lipid peroxidation measuring the plasma malonaldehyde (MDA) together with hydroxyalkenals (HALK).

Animals of group HR exhibited a significantly superior neurologic outcome compared to those of group C at all three consecutive assessments over time (post resuscitation p=0.006, at 8 hours p=0.003 and at 24 hours p=0.007). The levels of MDA and HALK are lower in group HR compared to C (p=0.005). Additionally, in group CC these molecules increase significantly at reperfusion compared to their reference levels (p=0.05).

Hypoxemic reperfusion during resuscitation from a severe ischemic cerebral insult improves the neurologic outcome compared to the classical hyperoxemic reperfusion and this is additionally confirmed by the decreased production of the molecules of lipid peroxidation.

Tardive Dyskinesia-Like Syndrome in a Patient with Hepatic Encephalopathy

Jennifer S. Rob, MD, Edward Feller, MD

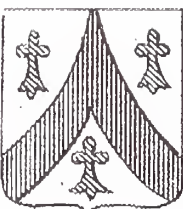
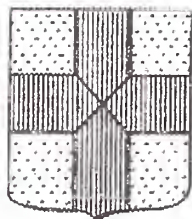
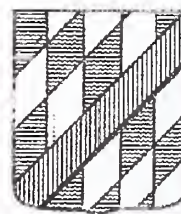
THE MIRIAM HOSPITAL/RHODE ISLAND HOSPITAL

Hepatic encephalopathy is a common clinical diagnosis that encompasses a wide range of symptomatology. Severity may vary from no symptoms or subtle shifts in personality to profound coma. We recently evaluated a patient with tardive dyskinesias as an initial feature of hepatic encephalopathy. We report this case to alert clinicians to this rare manifestation of a common problem.

A 79 year-old woman presented with a one-week history of increasing confusion and a two-day history of involuntary oral and lingual movements. Her past medical history was significant for hypertension, congestive heart failure, myelodysplastic syndrome, diverticulosis, bilateral mastectomies for breast cancer and cryptogenic cirrhosis. Medications on admission included furosemide, lisinopril, sulindac; she denied taking any sedatives or hypnotics. Physical examination was notable for persistent oral and lingual dyskinesias. Neurologic exam was otherwise negative. No stigmata of liver disease were evident. Laboratory tests showed thrombocytopenia, anemia, hypokalemia, and an elevated ammonia level of 99 $\mu\text{mol/L}$. CT scan of her head revealed white matter wash out and a small left parietal calcified meningioma without mass effect or edema

and no other findings. She was treated with lactulose with subsequent resolution of all symptoms.

The pathophysiology of hepatic encephalopathy, previously to be directly caused by elevated ammonia levels, may be related to over-stimulation of GABA receptors in the central nervous system, resulting in inhibitory type effects: depression in level of consciousness and motor function, altered sleep patterns with characteristic EEG findings. Hepatic encephalopathy has been cited as more likely to be associated with extrapyramidal symptoms such as muscular rigidity, bradykinesia, Parkinsonian-like tremors, and dyskinesias than other metabolic encephalopathies. Because the prognosis of hepatic encephalopathy is closely related to the identification and removal of a precipitating factor and 50% of cirrhotics die within one year of their first episode of hepatic encephalopathy, early diagnosis and treatment are crucial. Hepatic encephalopathy may present atypically and, in rare cases, as a movement disorder called non-Wilsonian hepatolenticular degeneration. As with Wilson's disease, the movements may resolve with treatment. Clinicians should consider decompensated liver disease when evaluating patients with movement disorders.



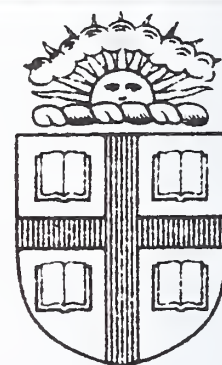
➔ *Forthcoming* ◀

Nutrition: A CME Issue

Medicine & Health/Rhode Island is pleased to dedicate the November 2000 issue to nutrition. This issue will be guest-edited by Charles Eaton, DM.

Brown University School of Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide Continuing Medical Education for physicians.

Brown University School of Medicine designates this educational activity for a maximum of 2 hours in Category 1 credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.



Barriers to the Provision of Child Safety Restraint: Anticipatory Guidance Among Rhode Island Pediatricians

Colette C. Mull, MD, Marilyn C. Li, MD, Amy Rosenthal, MPA, Scott D. Berns, MD, MPH

Motor vehicle-related injury is the leading cause of death and disability among children in the United States.¹ The majority of childhood health care dollars are spent on injury.² In Rhode Island, total costs for acute care treatment alone average approximately \$20 million per year.³ Motor vehicle occupant injury accounts for the highest costs associated with pediatric injury.¹

The child safety restraint (CSR) is the most effective passive strategy available in the prevention of pediatric motor vehicle occupant injury. We define CSR as a safety seat for the child under 40 pounds, a booster seat for the child over 40 pounds who is too small for the lap shoulder harness, and a lap shoulder harness for all other children, including adolescents. Safety restraints reduce health care costs by preventing injuries.⁴⁻⁹ In the subset of restrained children who require hospitalization for motor vehicle occupant injury, their use results in the consumption of fewer resources.¹⁰

Since the development and marketing of child safety seats, motor vehicle-related morbidity and mortality in the 0-4 years age group has decreased substantially.⁸ However, uneven and insufficient reductions in injury and fatality rates across all pediatric age groups are best explained by a lower-than-desirable rate of appropriate CSR use,⁹⁻¹¹ compounded by a well-documented decrease in CSR use with increasing age,¹¹⁻¹⁴ and frequent incorrect CSR use.¹⁵⁻¹⁹ Legislative action, strong enforcement of existing laws, community education, and anticipatory guidance (AG) are active strategies used to promote CSR use.

Rhode Island child restraint and safety belt use law, effective on July 1, 1998, states that any child under the age of 4 years must be properly restrained in the backseat in a federally approved child restraint seat while being transported in a motor vehicle. Children under the age

of 6 years old must be in a safety belt system in the back seat. The preceding are primary offenses until the age of 13, when the safety belt law becomes a secondary offense.

The safest place for children under 12 is in the middle of the back seat. If a child must be buckled in the front seat, particularly with an active air bag system, the child should be properly restrained and the seat should be moved back as far as possible from the dashboard to minimize risk of injury to the child in case of a car crash.

Our study addressed AG. Childhood injury prevention AG is defined as the provision of counseling to a child/guardian in the area of safety behaviors specific to that child's age and developmental stage, at each well-child visit, reinforcing the message at all interim visits.²⁰ With regard to CSR use, optimal AG should provide information on the ideal type of CSR for the child's weight, the child's position in the CSR, and the correct use of that CSR, including its placement in the motor vehicle. Actual demonstration of correct CSR use by the pediatrician to the patient/guardian has been recommended by some authors as an essential part of this AG.^{17,21}

Medical organizations provide guidelines: the American Medical Association's (AMA) Guidelines for Adolescent Preventive Services (GAPS),²² the Maternal and Child Health Bureau's Bright Futures,²³ and the American Academy of Pediatrics (AAP) Family Guide to Car Seats.²⁴ A 1975 survey revealed that less than 5% of 1,160 parents remembered their provider discussing CSRs with them.²⁵ Since 1983, the AAP has recommended that all children receive injury prevention AG as part of their primary care.²⁶ In a 1992 national survey, 60% of parents did not recall receiving injury prevention AG in their provider's office.²⁷

Abbreviations Used:

AAP	American Academy of Pediatrics
AG	anticipatory guidance
AMA	American Medical Association
CI	confidence intervals
CSR	child safety restraint
GAPS	Guidelines for Adolescent Preventive Services
TIPP	The Injury Prevention Program

Gielan, et al. documented that less than half of the well-child visits in one pediatric urban clinic included this form of AG.²⁸

In these studies, the reasons for less-than-ideal rates of AG by primary care providers were not documented. Cohen, et al. state that the social norms of medicine often prevent, rather than reinforce the practice of injury prevention AG.²⁹ For example, resident physicians are less likely to develop the clinical habit of consistent injury prevention AG if this practice goes unrewarded by their preceptors and/or if they are not held accountable for AG on the American Board of Pediatrics' certification examination.³⁰

Our study sought to identify barriers to CSR AG by primary care pediatricians. We hypothesized that time constraints in a pediatrician's workday, patient age greater than four years, and a patient's/guardian's inability to understand English have a negative impact on the pediatrician's provision of CSR AG.

METHODS

A cross-sectional mail survey of Rhode Island primary care pediatricians was employed, based on the American Academy of Pediatrics' Fellowship Directory, Brown University's Department of Pediatrics' list of community pediatricians, and Rhode Island telephone books to assemble our list of 130 Rhode Island pediatricians.

Two months prior to the study, seven members of the Brown University/

**Table 1. Characteristics of Survey Respondents' CSR AG Frequency of Delivery at Designated Well-Child Visits
A Summary**

Visits Frequency Number (%)	0-4 years old (n*=77) ⁺	>4 - 12 years old (n*=77) ⁺	>12 years old (n*=79) ⁺
Less Frequently	17 (22.1)	31 (40.3)	35 (44.4)
More Frequently	60 (78.0)	46 (59.8)	44 (55.7)
Missing ⁺⁺	2	2	0

* n=number of survey question respondents

⁺ n is not equal to 79 because two survey respondents did not report their frequency of CSR AG delivery for this visit category or stated that this survey question was not applicable to her/his situation.

⁺⁺ "Missing" refers to the number of survey respondents who did not answer the question posed or stated that the question was not applicable to her/his situation

Hasbro Children's Hospital Pediatrics Residency Program participated in a pilot project to assess the survey questions. A five-page, 16-item questionnaire was hand-delivered to each of the seven house staff members with an accompanying request for a written critique of the survey. All pilot surveys were returned, with written critiques; and the survey was modified accordingly.

Subsequently, 130 Rhode Island primary care pediatricians were mailed a self-administered, four-page, 10-item questionnaire, regarding the demographic makeup of his/her patient population, the frequency and content of his/her AG practices in the area of motor vehicle CSR use, and the factors which affect his/her decision to provide this AG. Survey items consisted of single-answer, Likert scale type, and multiple-choice questions with the opportunity for the respondent to write-in alternative answers. The initial survey, if not returned, was followed by as many as two monthly reminder surveys. Participant-to-researcher confidentiality was ensured by engaging an unbiased third party to conduct all communications between the research team and the survey pool.

Survey responses were analyzed, using Statistical Analysis System, version 6.11, software (SAS) (SAS Institute, Inc., Cary, North Carolina). The dependent variables studied were time constraints in a pediatrician's workday, patient age, and patient's/guardian's inability to understand English. To determine whether

the proportion of pediatricians reporting reduced likelihood of delivering AG differs significantly by patient age, 95% confidence intervals (CI) were calculated for differences between age-specific proportions. Similarly, a 95% CI was computed to characterize the proportion of pediatricians who stated reduced likelihood of CSR AG provision to patients/guardians unable to understand English. Statistical significance was established at an alpha less than 0.05.

RESULTS

Seventy-nine of 130 pediatricians (61%) returned the questionnaires. The mean respondent age was 45.1 years

(standard deviation (SD) = 11.1 years). The mean number of years out of residency was 15.5 years (SD = 11.2 years). Of the 79 pediatrician-respondents, 52 (66%) stated that they alone are responsible for the delivery of AG in their practice, while 26 (33%) stated that they share this responsibility with other health professionals in their practice. Only one pediatrician stated that another individual is the sole provider of AG in her/his practice. Other health professionals cited included nurse practitioners, nurses, and physician assistants.

Fifty-five of the 79 pediatricians (70%) described the age makeup of their practice population. The mean percentage of patients in the 0-4 year old age group, 44%, is slightly higher than that in the >4-12 year old age group, 33%, and higher than that in the >12 year old age group, 23%.

In detailing the content of the infant car seat AG, 55% of pediatricians stated that they discuss the importance of infant safety seat use, the mechanics of its use, and the details of booster seat use. In their child seat belt AG discussions, 42% stated that they review the timing of the transition from infant safety seat/booster seat to CSR (lap shoulder harness), the importance and mechanics of CSR use, and the importance of seating children in the rear seat. Pediatricians also mentioned adult seat belt use and CSR laws as items discussed with

Table 2. Patient Age as a Factor of Influence on Survey Respondents' Motor Vehicle CSR AG Delivery

Effect Number (%) Visits	Less likely to deliver AG	No effect	More likely to deliver AG	Missing
0-4 years old (n*=77) ⁺	7 (9.1)	37 (48.1)	33 (42.9)	2
>4-12 years old (n*=77) ⁺	19 (24.7)	41 (53.2)	17 (22.1)	2
>12 years old (n*=78) ⁺	29 (37.2)	40 (51.3)	9 (11.5)	1

* n=number of survey question respondents

⁺ n is not equal to 79, n=78 or 77, because either one or two survey respondent(s) did not provide information on how that particular age influences her/his CSR AG delivery or stated that particular age category was not applicable to her/his situation.

⁺⁺ "Missing" refers to the number of survey respondents who did not answer the question posed or stated that the question was not applicable to her/his situation

patients and/or their guardians.

1) Time Constraints:

Of the 78 respondents who commented on time constraints in their workday, 41% reported that they are less likely to discuss CSR use if they feel that the time allotted for a well-child visit is limited. Five pediatricians specifically mentioned that a patient/guardian often presents with an unexpected agenda of issues, consuming time otherwise allotted to preventive medicine discussions.

2) Patient Age:

For the purposes of data analysis, the frequency of CSR AG variable was collapsed into two categories: less frequently ("never," "rarely" and "occasionally"), and more frequently ("frequently" and "always").

Results of the survey indicate that younger patients were significantly more likely to receive CSR AG than older ones. More than 40% of pediatricians infrequently provided CSR AG to patients over 4 years of age (Table 1). By comparison, only 22% of pediatricians infrequently provided this counseling to patients 4 years of age and under ($p < 0.05$) (Table 1). Regarding factors which have an effect on the provision of CSR AG, respondents revealed that as patient age increases, they are less likely to deliver CSR AG (Table 2).

3) Language:

More than half of 72 survey respondents (57%) are unable to provide CSR AG in a language other than English. In addition, 47% (95% confidence interval (C.I.) ± 0.11) are less likely to provide CSR AG if a patient/guardian is unable to understand English ($p < 0.05$). However, respondents stated that their patient's race/ethnicity and type of medical coverage have no influence on their delivery of CSR AG.

In addition, self-perceived change in the respondents' delivery of CSR AG was examined over the five-year period from 1990 to 1995. Twenty-one percent of the respondents felt their delivery had changed over this period; when described, these changes generally reflected a heightened awareness of CSR AG.

DISCUSSION

Our study results confirm our hypotheses. The barriers to the pediatrician's provision of CSR AG include her/his workday's time constraints, patient age greater than four, and a patient's/guardian's inability to understand English.

The safest place for children under 12 is in the middle of the back seat. If a child must be buckled in the front seat, particularly with an active air bag system, the child should be properly restrained and the seat should be moved back as far as possible from the dashboard to minimize risk of injury to the child in case of a car crash.



1) Time Constraints:

Pediatricians face the challenge of continuing to provide quality primary care as their number of daily patient visits grows, the complexity and diversity of their patients' problems increase, and the reimbursement for preventive services remains uneven. This phenomenon may account in part for the negative impact of time constraints on CSR AG delivery.

Although most pediatricians in our study deliver CSR AG themselves (66%) at the time of the well-child visit, 33% of our respondents rely on nurses and nurse practitioners to assist them in this task. These pediatricians may be ensuring that time constraints in their workday do not compromise their delivery of quality health care. Stone suggests that "collaborative teams of pediatricians and pediatric nurse practitioners" can provide "high-quality, cost-effective" pediatric care.³¹

2) Patient Age:

Patient age greater than four years had a negative impact on the pediatrician's delivery of CSR AG. Observational studies have shown that CSR use dramatically decreases with age: 84% for 0-4 year olds; 57% for 5-11 year olds; and 29-57% for 12-18 year olds.^{11,12} Some authors have even identified discrepancies in usage rates between infants (0-12 months old) 76%, and toddlers (1 to 4 year olds) 43%.¹² It is possible that the inverse relationship between age and pediatrician's CSR AG delivery may be associated with that between age and CSR use.

Pediatricians may deliver CSR AG less frequently to the older child for a number of reasons. The breadth and depth of the older child's single yearly well visit may render it difficult to provide complete well-child care. Given the AAP's early emphasis on the use of infant car seats (1980-1987),³² despite the increasing use of TIPP since its inception in 1983,³³ primary care providers may be conditioned to provide CSR AG with greater frequency to infants' guardians than to older children and their guardians. Some pediatricians may not know that their state mandates motor vehicle safety restraints for older children.

Of all age groups, adolescents have the lowest rate of CSR use.^{13,14} Adolescents are both drivers and passengers. In this stage of risk-taking behaviors fueled by peer pressure and feelings of invulnerability, adolescents' driving inexperience, coupled with use of alcohol and/or other substances of abuse, accounts in large part for an associated mortality rate 10 times higher than their younger motor vehicle occupant counterparts (under 10 years of age).^{1,13} The pediatrician may understandably perceive delivering CSR AG to the adolescent as a formidable task.

It is unclear whether increased frequency of CSR AG provision to older children and their guardians would actually increase their CSR use. It is possible that CSR use declines with age as "independence" develops.

3) Language:

Another barrier to the provision of CSR AG is a patient's/guardian's inability

ity to understand English. Numerous observational studies have documented low rates of safety restraint use among racial/ethnic minority populations.³⁴⁻³⁷ Multiple explanations for this low usage rate have been suggested. Our survey results support the argument¹⁷ that such populations, often comprised of recent immigrants, may not understand information in English.

Rhode Islanders speak at least 24 languages.³⁸ Our study indicates that more than half of Rhode Island pediatric offices do not relay important safety information to this sizable segment of the population. In addition, we have shown that a patient's/guardian's inability to understand English is a factor in whether or not CSR AG is discussed at a well-child visit. However, the extent to which language is a barrier to the provision of CSR AG likely varies with patient mix and practice location.

There are a number of possible approaches to addressing this barrier. Several pediatricians in our study required non-English-speaking patients/guardians to be accompanied by at least one person able to understand/speak English. Many Rhode Island health clinics hire non-physician professionals (e.g., nurses, medical assistants, receptionists) from the communities they serve and require them to be proficient in not only English but in at least one other language. Additionally or alternatively, pediatricians can attempt to acquire a working knowledge of the language(s) commonly spoken in their practice population. Also, pediatrician access to multi-lingual injury prevention educational materials (e.g. brochures, videotapes) would help remove the language barrier to pediatricians' CSR AG provision.

LIMITATIONS

There are a number of limitations to this study. With a survey response rate of 61%, our results might not reflect the practices of other pediatricians in the state or in the country. As a self-selected group, these pediatricians are more likely than not to be motivated practitioners, comprehensive in their delivery of primary care, comfortable with their practice of CSR AG, and interested enough in academic medicine to respond

to a research survey. Reporting bias makes it likely that these same respondents overstated their CSR AG activities. It is possible that results of this survey reflect how respondents feel they ought to deliver CSR AG and do not constitute an accurate representation of their practice of CSR AG. The limitation of small sample size and generalizability would be best addressed by a follow-up survey of a larger population of pediatricians (e.g. members of the AAP). Finally, our survey instrument was created specifically to assess time constraint, patient age, and language as barriers to the provision of CSR AG. Other barriers, suspected and unknown, were not addressed in our study.

CONCLUSIONS

Our study documents less-than-widespread CSR AG provision by primary care pediatricians in Rhode Island. It identifies three barriers to pediatrician provision of CSR AG: 1) time constraints in a pediatrician's workday, 2) patient age greater than four years, and 3) a patient's/guardian's inability to understand English.

IMPLICATIONS FOR PREVENTION

A child's pediatrician, viewed as a respected health advisor,²⁷ is a guardian's first choice for information on injury control and child safety.³⁹ She/he is able to change a guardian's knowledge base and behaviors in the area of injury prevention.^{21,40-44} However, parental surveys have claimed low rates of provider injury prevention counseling delivery^{25,27} while there is also evidence that some pediatricians may feel uncomfortable providing such counseling.³⁰

Although not specifically addressed in our study, doctors also may lack knowledge about correct usage of CSRs. There are a number of possible solutions; e.g., 1) trainings for medical providers, 2) referrals for patients about relevant community agencies and services, 3) simple, up-to-date literature on CSRs geared at educating providers, and 4) utilization of nurses and health educators who have been trained by the National Highway Traffic Safety Administration to conduct CSR safety checks for community residents.

Our study suggests that time constraints, patient age, and language hinder the provision of injury prevention anticipatory guidance. Physician extenders, such as nurse practitioners, nurses, and physician assistant, may improve rates of counseling. So may educational materials and instruction delivered in the language of the patient.

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The Emerging Role of Uterine Artery Embolization in the Management of Symptomatic Uterine Fibroids

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Leiomyomata or fibroids have an estimated prevalence of 20-40%¹ in women over 35 years of age and cause symptoms in 20-40% of patients.^{1,2} Symptoms are life-altering for many women and result in an estimated 2-4 million person-days per year lost to work or other activities.³ The minimum estimated direct cost of treating uterine myomata in the United States is over \$1 billion per year.⁴ Medical therapy may relieve symptoms while surgical therapy may be curative. Symptomatic leiomyomata result in approximately 200,000 hysterectomies and 40,000-60,000 myomectomies per year in the United States.^{1,5} Uterine Artery Embolization (UAE) has been used over the past 7 years⁶ to treat women with symptomatic leiomyomata. The treatment offers a non-surgical treatment option to many patients with symptomatic fibroids. This article reviews briefly the natural history and treatment of fibroids and updates the reader on the current status of UAE.

NATURAL HISTORY

Fibroids are steroid-hormone (estrogen and progesterone) responsive tumors, which usually grow slowly during the child-bearing years and regress after menopause.^{1,2} Hormone-replacement therapy alters this normal progression in some patients and thereby "deprives both the gynecologist and the patient of nature's respite."⁷ Hormonal alterations may cause fibroids to enlarge rapidly during pregnancy. A rapidly enlarging fibroid in a non-pregnant female or growth in a post-menopausal female should prompt evaluation to exclude malignancy. Sarcomatous degeneration is exceedingly rare.² Uterine leiomyosarcoma, a rare tumor that does not appear to be related to leiomyomata, may be discovered incidentally at the time

of surgery for leiomyomata (0.1-0.3% pre-menopausal, less than 1% post-menopausal¹).

Leiomyomata cause symptoms which range in severity from mild to incapacitating.² Most patients complain of heavy and/or irregular periods, which may result in anemia. Bulk symptoms, also frequent, are related to the size of the myomatous uterus and mass effect upon adjacent organs. These include pelvic pain, pressure, bloating, constipation, back pain, leg swelling, and urinary frequency. Less commonly, fibroids result in dyspareunia, early fetal loss, and hydronephrosis.^{1,2} Fibroids have been implicated as contributing to infertility, although the association remains unproven.⁴

PATIENT EVALUATION

Patient evaluation will vary according to symptomatology. One must exclude malignancy in patients with abnormal uterine bleeding. This requires a Pap smear and a thorough history and complete gynecologic examination by a skilled examiner. Many gynecologists also advocate a test (endometrial biopsy, diagnostic hysteroscopy, or hysterosonography) to exclude an intrauterine lesion. Imaging tests (ultrasound or MRI) are indicated both in patients with abnormal bleeding and those with bulk symptoms. These will be discussed below. Blood tests for patients with abnormal uterine bleeding vary according to physician. Most agree that Hb/Hct is indicated to exclude anemia, especially if surgery is being contemplated. Some also advocate a coagulation profile and various hormonal tests to detect imbalances that may relate to heavy menses (FSH, TSH, Prolactin, etc). For patients contemplating UAE the only required blood test is Hb/Hct.

Abbreviations Used:

AVM	arteriovenous malformation
D&C	dilation and curettage
FSH	follicle-stimulating hormone
MRI	magnetic resonance imaging
NSAID	non-steroidal anti-inflammatory drug
PCA	patient-controlled analgesia
PVA	polyvinyl alcohol
TSH	thyroid-stimulating hormone
UAE	uterine artery embolization
US	ultrasound

Patients with a history of bleeding diathesis also require a coagulation profile.

For patients with bulk symptoms the work-up is only slightly different. The cornerstone of the evaluation again is a thorough history and complete gynecologic examination by a skilled examiner, and a Pap smear should be performed. Imaging tests are used to confirm physical exam findings, evaluate both the uterus and the ovaries, and to measure the size, number, and precise location of fibroids. It is important to note the exact location (Figure 1) of fibroids (intramural, submucosal, subserosal, exophytic, or pedunculated) because location can effect treatment options. Ultrasound offers the advantage of a slightly lower cost with the disadvantage of decreased anatomic detail and poor reproducibility of measurements. MRI offers the advantages of superior anatomic detail, more reproducible measurements, and improved detection of adenomyosis. A recent study also suggests that MRI data may be useful in predicting successful response to UAE.⁸ Imaging tests can also help to exclude other sources of symptoms, including both gynecologic (ovarian cysts/tumors, endometriosis, pelvic inflammatory disease, adenomyosis) and non-gynecologic etiologies (inflammatory bowel

disease, hernia, other pelvic mass from bone, bowel, or nerve). Routine bloodwork is not needed for patients with pain unless surgery is contemplated.

MANAGEMENT

Treatment of fibroids is dependent upon symptomatology. Asymptomatic fibroids require no treatment. Medical treatment for patients with menometrorrhagia consists primarily of hormonal therapies.^{2,7} These include progestins, combination oral contraceptive pills, or GnRH analogues. Any estrogen (exogenous or endogenous) may cause an increase in the size of fibroids in certain patients and worsen symptoms. GnRH analogs decrease estrogen levels, shrink fibroids, and reduce uterine volume by 50% in 85% of patients.^{2,9} Menopausal side effects are intolerable for some patients. Furthermore, most fibroids will regain their original size 4-6 months after cessation of these agents.^{1,2} They are used primarily as temporizing agents in peri-menopausal patients or as pre-operative therapy in anemic patients.¹ GnRH analogs are usually discontinued prior to myomectomy or embolization. The induced decrease in vascularity has been reported to make surgery more difficult¹⁰ and may decrease flow of embolic agent to the fibroid.

Patients with pain are treated primarily with analgesics. NSAIDs are the mainstay of therapy. Oral narcotic analgesics may be prescribed safely to patients with severe dysmenorrhea limited to a few days duration each month, but are not generally recommended for chronic pain because of problems with dependency.

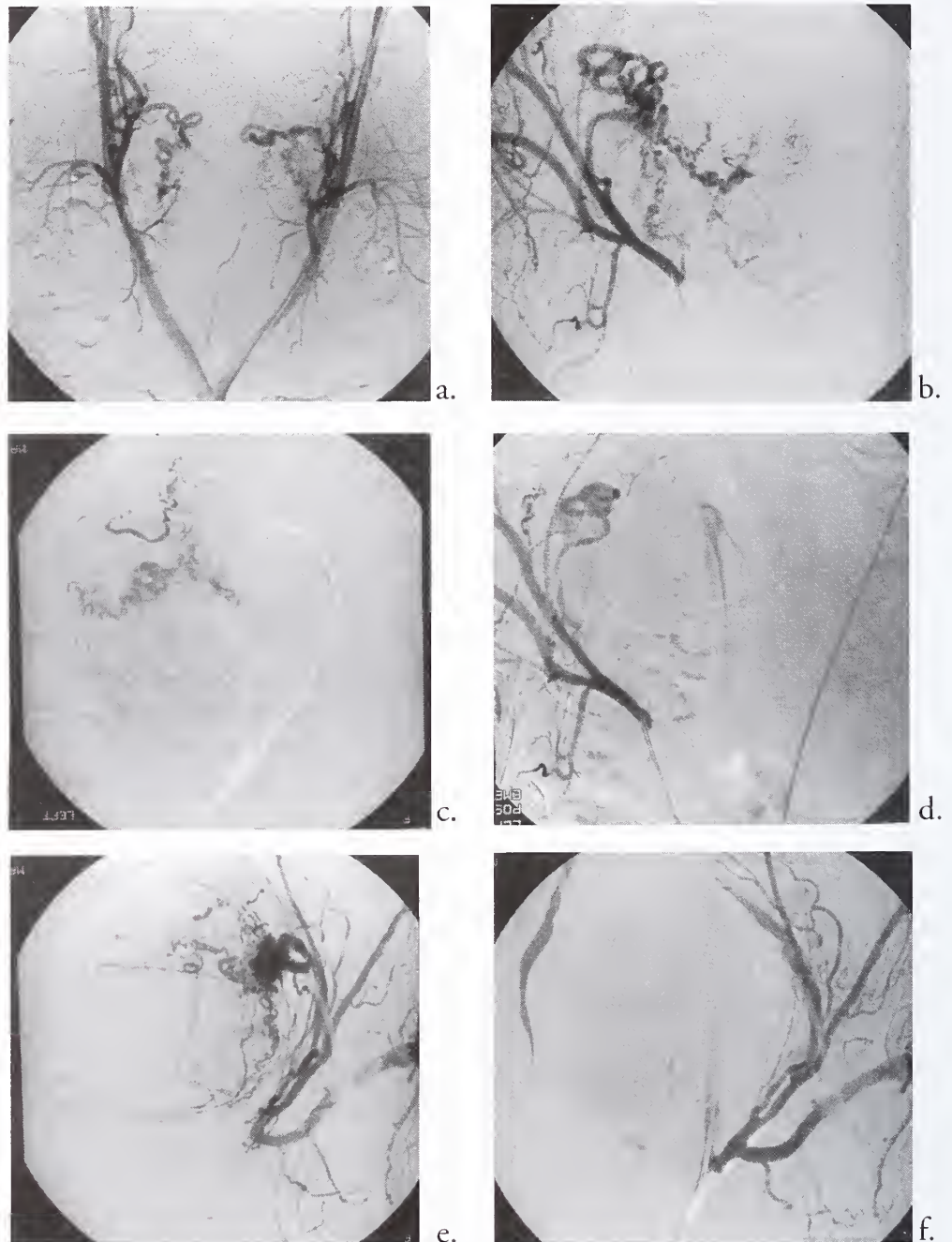
Because medical therapy fails to control symptoms in 50-70% of patients, many will require more invasive treatment. Hysterectomy is the most common invasive treatment for fibroids in the US. The procedure has a major complication rate of 1-5% and a death rate of 0.1%.¹¹ Approximately 0.5-10% of patients will require blood transfusion related to intra- or peri-operative blood loss.¹¹ Both rates vary according to technique (vaginal, laparoscopic, or abdominal).¹¹ Hyster-

ectomy has the advantage of being curative, but entails anesthesia, a significant recovery period, and removal of an organ that some women may wish to preserve.

Myomectomy is a technique by which individual myomata are surgically removed without removing the uterus.^{2,9,12} Myomectomy may be performed using an abdominal, hysteroscopic, or laparoscopic approach. Complication rates are similar to hysterectomy with a slightly higher transfusion rate.^{2,9,12} Symptomatic

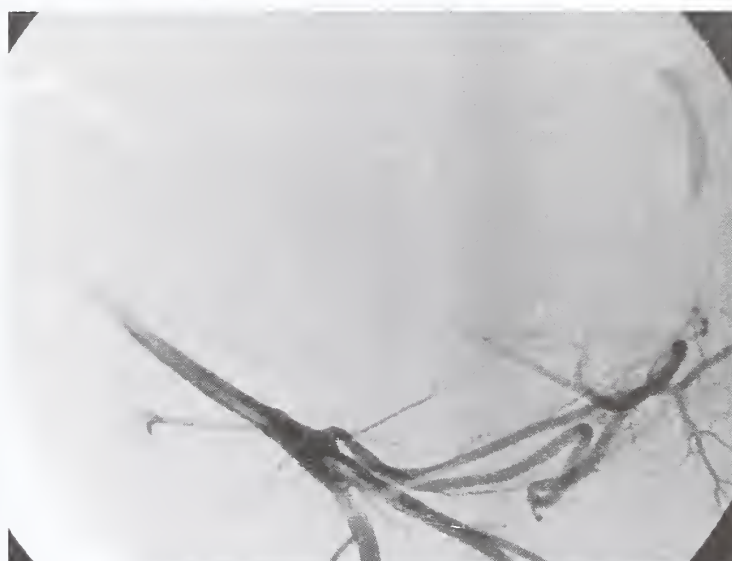
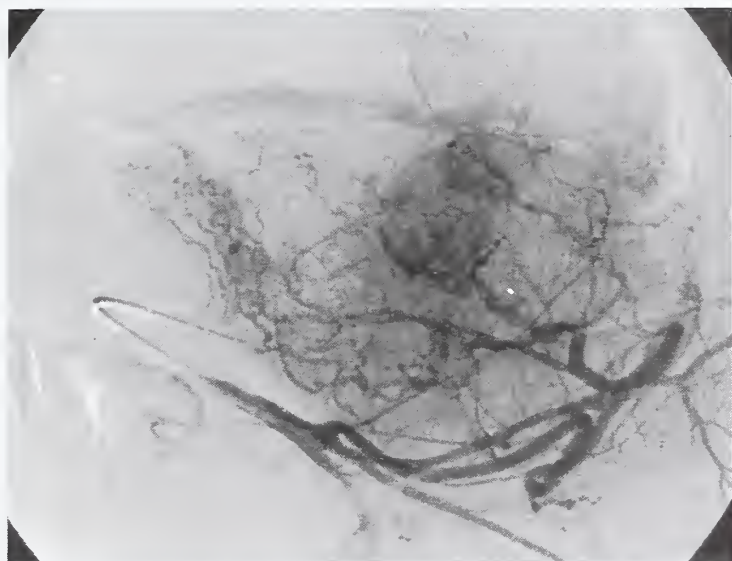
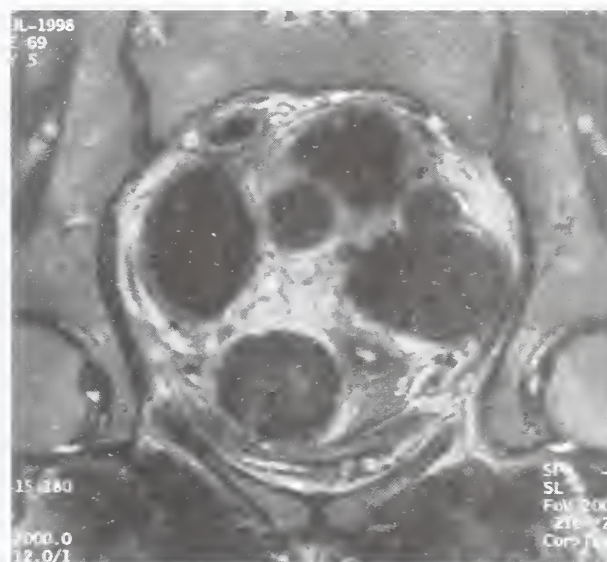
improvement is reported in approximately 81% of patients. Recurrence of symptoms, resulting from regrowth of residual fibroid tissue or growth of other fibroids, occurs in 15-27%, with approximately 10% eventually requiring re-operation.^{2,12} Because the technique preserves the uterus, future childbearing is possible. Although there have been reports of rupture of gravid uteri following myomectomy,¹³ it remains the standard of care for patients desiring future pregnancy.

Myolysis is a newer technique by



Case 1. Images obtained at Rhode Island Hospital of a 40yo G1P1 female with a history of severe menometrorrhagia and pelvic pain. Physical exam suggested a 12 week-size uterus. Ultrasound demonstrated multiple fibroids, the largest of which measured 5x5x6.5 cm. (a)

Pelvic arteriogram demonstrates enlarged uterine arteries. (b) Selective left internal iliac injection identifies the origin of the left uterine artery. Note the increased vascularity related to the myomatous uterus. (c) Selective catheterization and advancement of a microcatheter into the distal uterine artery. (d) Post-embolization injection demonstrates stasis in the left uterine artery and absence of flow to the uterus. (e) Pre-embolization right internal iliac artery injection. Note the hypervascular, myomatous uterus. (f) Post-embolization right internal iliac artery injection.



Case 2. Images obtained at Rhode Island Hospital of a 36yo G1P0 female not desiring future pregnancy with a 10-year history of menometrorrhagia, urinary frequency, and dyspareunia. The patient had been treated with GnRH analog therapy and myomectomy without relief of symptoms. (a) US demonstrates myomatous uterus causing mass effect upon the bladder. (b) MRI confirms enlarged (16 week) uterus with multiple leiomyomata. (c) Right internal iliac artery injection shows enlarged uterine artery with branches stretched around hypervascular fibroids. (d) Post-embolization right internal iliac artery injection confirms stasis in uterine artery. The left uterine artery was also successfully embolized.

which fibroids are ablated using laser, bipolar needles, or cryolysis.¹⁴ Myolysis also allows preservation of the uterus. The technique is less widely available than myomectomy and is most useful when the number and/or size of fibroids is small. Because of limited experience, the complication rate is not known. The significance of post-procedure adhesions,¹⁴ found in a substantial number of patients, requires further study. Rupture of a gravid uterus following myolysis has also been reported.¹⁵ Experience with this technique is limited and investigation is ongoing.

UTERINE ARTERY EMBOLIZATION

UAE offers the only truly non-surgical treatment for symptomatic leiomyomata not responsive to conservative measures. Although the application of embolotherapy to uter-

ine fibroids is relatively new, pelvic embolization has been carried out safely for over 25 years. UAE to control post-partum hemorrhage was first described in 1979.¹⁶ Since that time, applications have broadened to include treatment of ectopic pregnancy, uterine AVMs, high bleeding risk obstetrical patients, and pre-operative embolization to decrease bleeding in cases of large uterine tumors.⁶

UTERINE ARTERY EMBOLIZATION TO TREAT LEIOMYOMATA

The application of UAE in the treatment of leiomyomata came serendipitously. Ravina, et al.⁶ were performing pre-operative UAE on patients with large fibroids to decrease blood losses at planned surgery. Many patients reported a significant improvement in symptoms and some refused surgery. Physical examination and ul-

trasound confirmed a significant decrease in the size of myomatous uteri. The treatment was then offered as an alternative to surgery in select patients under a study protocol. Since that time, multiple centers have reported results using this technique to treat symptomatic fibroids.^{6,8,17-23}

UTERINE ARTERY EMBOLIZATION- TECHNIQUE

UAE is performed using local anesthesia and conscious sedation. Most practitioners administer prophylactic antibiotics. The procedure is generally performed from a standard common femoral artery access. Selective catheterization of each internal iliac artery is performed with a 4-5 French catheter (see cases 1 and 2). Arteriography is performed to locate the origins of the uterine arteries. The uterine arteries are selectively catheterized stud-

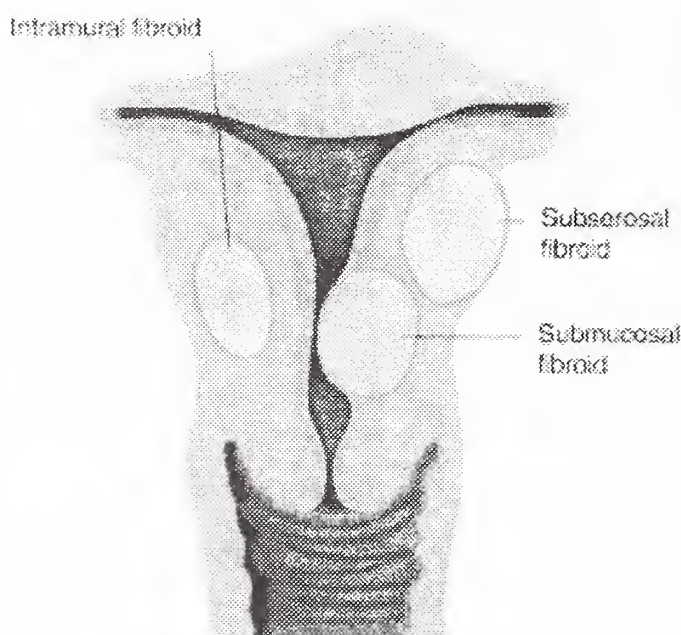


Fig. 1.

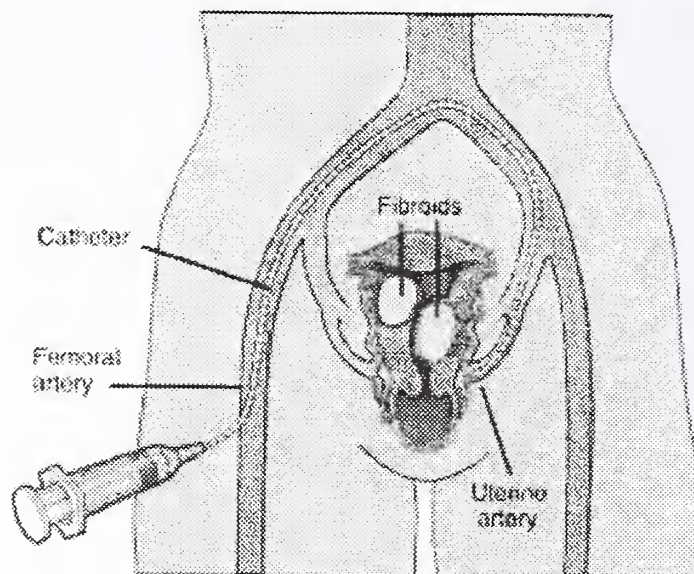


Fig. 2

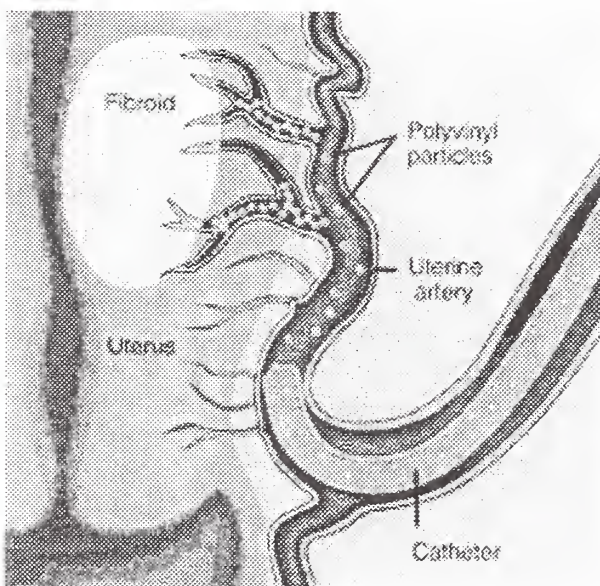


Fig. 3

Figure 1- Schematic diagram of the various locations of uterine leiomyomata. (Used with permission of the Society of Cardiovascular and Interventional Radiology).

Figure 2- Depicts selective catheterization of the uterine artery. (Used with permission of the Society of Cardiovascular and Interventional Radiology).

Figure 3- Schematic view of embolization occurring via injection of the PVA particles into the uterine artery. This results in vascular occlusion and thereby deprives the fibroid of its blood supply. (Used with permission of the Society of Cardiovascular and Interventional Radiology).

ied. Embolization is carried out by slowly injecting polyvinyl alcohol (PVA) particles under fluoroscopic monitoring until the vessel is completely occluded, shown diagrammatically in figures 2 and 3. PVA particles have been used safely for 30 years. The appropriate size of particles is currently an area of debate.¹⁷⁻²³ Although smaller particles (150-300 microns) may penetrate the vasculature more deeply and result in more complete embolization,¹⁷ they appear to cause more pain¹⁸ and may increase infection rates for large fibroids.²⁴ Most investigators in the US currently use 500-710 micron particles. Some authors complete the embolization by placing a gelfoam pledget in the uterine artery.^{18,19,23} The procedure takes between 45 and 135

minutes to complete. Patients receive NSAIDS during and following the procedure. Narcotic analgesia and antiemetics are often required to control pain and nausea for the first 12 hours following the procedure. These agents can be conveniently combined and administered via patient-controlled analgesia (PCA) pump. Most patients can be switched to PO medication for pain/nausea control the following morning. Patients generally stay one night in the hospital²⁰⁻²² and are discharged the following day. Less often, patients may be discharged the same day or require 2-day admission. Most patients experience moderate pain for 3-5 days that can be controlled with PO pain medications. The mean time to return to normal activity is 8.9

days (range 2-18).²⁰

NORMAL POST-PROCEDURE COURSE AND COMPLICATIONS

Patients generally tolerate UAE well and complications occur infrequently. Groin hematoma or contrast reaction, the most common complications of arteriography, occur in less than 1%.¹⁰ Pain and nausea can be expected in all patients and is generally treated with PO medications. Occasionally patients will require re-admission for IV medication. Post-embolization syndrome (low-grade fever, leukocytosis, and pain) may be considered a normal response to UAE and is similar clinically to acute fibroid degeneration. This occurs to some extent in 10-40%^{21,10} of patients, but only

rarely requires readmission. More serious complications have been reported in 1-2% of patients.^{6,10,17-23} These result most often from an infection (endometritis, salpingitis, infected fibroid, etc) or from a retained necrotic fibroid. Infections usually respond to antibiotics. Rarely, an infection and/or retained fibroid will require surgical evacuation. The short-term rate of re-operation (i.e. hysterectomy following UAE) is approximately 0-2%.^{6,8,17-23} This compares favorably to the 1-5%¹¹ rate of unintended re-operation following hysterectomy. Most patients will experience a non-purulent vaginal discharge, which is thought to be the result of breakdown of the myoma related to post-embolization degeneration.^{19,22} Some patients may spontaneously pass fibroid tissue per vagina. This occurs more frequently in patients with submucosal fibroids.¹⁸⁻²¹ Although no deaths have been reported in the 4165 cases performed in the US, one associated death has been reported in the UK.^{24,25}

RESULTS OF UAE TO TREAT SYMPTOMATIC LEIOMYOMATA

A recent survey by the Society of Cardiovascular and Interventional Radiology reports that 4,165 UAE procedures have been performed in the US as of September 1999.²⁶ Technical success rates have been uniformly high (98-100%).¹⁸⁻²³ Patient satisfaction with the procedure²⁰⁻²² has also been high with 82-94%²⁰⁻²² of patients stating that they would choose the procedure again. An outcomes study has validated significant improvement in symptoms as well as health-related quality of life.²⁷

Objective tests including physical examination, US, and MRI have confirmed significant decreases in both the volume of the uterus (43%²⁰-50%¹⁹) and dominant myomata (49%²⁰-69%¹⁹). Menometrorrhagia is markedly decreased in 80-100% of patients. Bulk symptoms are markedly improved in 80-100%. Clinical improvement has been consistently demonstrated worldwide in approximately 85% of patients. Results in Rhode Island mirror those achieved elsewhere. These

results compare favorably with the 81% of patients who report improvement following myomectomy. Although Ravina et al have follow-up to 7 years, mean follow-up for other series ranges from 8.7-16.3 months. To validate the durability of the procedure, longer follow-up will be needed. Fibroid regrowth, which can occur in 15-27%² of patients following myomectomy, has not been documented during the limited follow-up currently available.

UTERINE ARTERY EMBOLIZATION AND FERTILITY

The long-term impact of UAE on fertility and/or childbearing is unknown. Although clinical effects to date have been minimal, UAE could theoretically have a negative effect on fertility/childbearing via effects of embolization and/or radiation on the endometrium, myometrium or ovaries. Each of these theoretical mechanisms will be discussed below.

Amenorrhea has been reported in 1-2% of patients undergoing UAE.¹⁷⁻²³ Whether this results from premature ovarian failure, endometrial ischemia or the normal climacteric process is unclear. As most patients are perimenopausal at the time of UAE it is difficult to determine the true effect of the procedure on ovarian function relative to the climacteric process.

Potential causes of premature ovarian failure include non-target embolization (resulting in decreased blood flow to the ovaries) and/or radiation effects. Because the uterine arteries communicate with the ovarian arteries via anastomoses with the tubal arteries,²⁸ nontarget embolization of the ovarian blood supply is theoretically possible. Given the microscopic nature of these anastomoses relative to the size of the particles, however, the clinical significance of this is doubtful. The mean estimated ovarian radiation dose related to UAE is 22.34 cGy²⁹ (Barium enema = 0.7 cGy, abdomen/pelvic CT = 2 cGy). Although the effect of this level of exposure on ovarian function is unknown, extrapolation of data from pelvic radiation therapy studies may allow some

useful comparisons. Temporary and/or permanent amenorrhea has been reported in patients undergoing pelvic irradiation for Hodgkin's disease;³⁰ however, this occurs at doses that are 10-100 times higher than those experienced in UAE. Although it appears that the radiation dose from a standard UAE would have no significant effect on ovarian function, further data will be needed to validate such a conclusion.

It is also possible that the decreased uterine artery blood supply following embolization may decrease endometrial flow enough in some patients to decrease endometrial viability and cause amenorrhea. Because over 98% of patients experience normal menses following UAE the clinical significance of this mechanism is also dubious.

Another theoretical concern is the ability of the embolized uterus to attain and sustain pregnancy. Although at least 7 patients are known to have carried babies to term following UAE to treat symptomatic fibroids, the potential for fetal growth restriction and uterine rupture following uterine artery embolization remains unknown. It is possible that the decreased uterine artery blood supply following embolization may decrease endometrial, myometrial, or placental integrity and/or ability to withstand pregnancy.

Until prospective trials are completed women should be informed that UAE may have a negative impact on fertility and/or childbearing. Myomectomy remains the standard of care for women who desire to become pregnant. When myomectomy is contraindicated UAE or myolysis may be acceptable alternatives.

UAE FAILURES AND SPECIAL CONSIDERATIONS

Technically successful UAE fails to improve symptoms in 10-15% of patients.^{6,8,17-23} Failures can be caused by underembolization, additional blood supply, or alternative diagnoses. Some failures cannot be explained. It is believed that UAE works by inducing necrosis of the leiomyomata related to ischemia induced by the arterial block-

ade. Pathological examination of uteri removed from patients who have undergone UAE confirms this theory, demonstrating hyaline degeneration in all large leiomyomata and in many small leiomyomata.³¹ Because of the extensive anastomotic network between uterine and ovarian arteries^{28,32} and potential for parasitization of other pelvic blood supply, some patients may fail simply because alternate sources provide blood to the myoma. Follow-up arteriography in a UAE clinical failure demonstrated an enlarged ovarian artery supplying the myoma.³²

Comorbid conditions are present in up to 85%²¹ of patients with leiomyomata, make it difficult to determine with certainty the true etiology of a patient's symptoms. Although UAE may effectively treat the leiomyomata, the comorbid condition may result in clinical failure.³³ This fact reinforces the importance of a thorough history, gynecological examination, imaging work-up, and appropriate lab tests prior to deciding upon appropriate treatment.

Submucosal or pedunculated fibroids warrant special consideration. Submucosal or pedunculated intracavitary fibroids have a higher incidence of expulsion (3-7%¹⁸⁻²³). These may pass spontaneously, but may become a nidus for infection and require surgical removal. Although such patients may be treated successfully with UAE, consideration should be given to hysteroscopic removal when treating a single dominant submucosal/intracavitary fibroid.²¹ Pedunculated exophytic fibroids may undergo necrosis of their stalk following UAE and become free within the pelvis or peritoneal cavity. These may potentially serve as a nidus for infection or compress bowel as they degenerate. Consideration of laparoscopic removal of such leiomyomata is prudent.

CONCLUSIONS

UAE has evolved as a highly promising non-surgical alternative for the treatment of symptomatic uterine leiomyomata. The procedure offers the advantages of conscious sedation rather than general anesthesia and a single

over-night hospital stay in most cases. Other advantages include the ability to treat multiple fibroids and the ability to preserve the uterus. Patients can expect to experience mild-moderate pain with some nausea. These symptoms are usually controlled with oral medications and rapidly subside over 3-7 days. Serious complications occur in less than 2%. Approximately 85% of patients report significant improvement or resolution of symptoms. As with any new treatment, long-term follow-up will be needed to document the durability of these results. Because the net impact of UAE on ovarian function, fertility, and child-bearing is unknown, patients should be advised of the potential negative effects. The procedure is ideally suited to patients not desiring future pregnancy who wish to avoid or have a contraindication to surgery. Success has also been reported in patients that have failed other uterine-preserving surgery. Consideration may be given to patients with comorbid conditions that fail conservative therapy. Myomectomy may be a better option for patients with a single submucosal or an exophytic pedunculated fibroid. This procedure is available at Rhode Island Hospital, Women & Infants' Hospital, and the Miriam Hospital. Investigation continues in Rhode Island as well as around the globe.

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Medical Error in the Physician Office: An Insurer's Perspective

Linda Greenwald, RN, MS

The 1999 Institute of Medicine study, indicating that between 44,000 and 98,000 patients die in American hospitals each year as the result of medical error,¹ put medical errors onto the radar screens of patients, health care providers, and insurers.

Medical errors happen because fallible human beings work in flawed systems. Some of the estimated one million patient injuries that are estimated to occur from medical error each year in the nation's hospitals² are the result of individual carelessness, oversight, or accident; more result from systems problems that involve several individuals and multiple departments.

Fully two thirds of the errors resulting in injury are thought to be preventable.² In an attempt to systematize efforts aimed at the prevention of medical error in the inpatient setting, federal, state, and institutional efforts have been proposed to examine the occurrence of such errors, determine their source, and propose corrective action.

Little such effort has been expended to stem the tide of errors occurring in physicians' offices. This article offers a view into some of those errors. It is not a comprehensive study because the data base is restricted to claims and suits, which represent only a small percentage of actual errors. However, if one assumes that allegations of negligence reflect at least a portion of some of the most egregious medical errors, it follows that a look at some of the claims and suits filed against physicians may give insight into at least a portion of the problem.

By one estimate, fewer than 2% of the 1% of the hospital patients injured as the result of medical error initiate a claim.³ Patients sue for many reasons, among them dissatisfaction with a physician they feel is not caring and compassionate,³ displeasure with a physician they perceive as disinterested or rushed, a breakdown in communication between

physician and patient,⁴ or anger at what the patient perceives as a betrayal of trust in the event of an adverse outcome or what he/she believes to be cover-up after an adverse outcome.⁴ If emotion often precipitates the decision to file a claim, quality of care is almost always the focus of the allegation.

ProMutual Group, a Massachusetts-based medical malpractice insurer, conducts ongoing research into its closed and open claims. The goal is to identify patterns of medical error so that physicians, once apprised of the risk areas particular to their specialty or their office practice, can take corrective actions.

A recently completed study revealed that of the 3400 claims closed in the five-year period ending December 31, 1998, 1085, or almost one third, were filed as the result of perceived negligence in the office. Of the total, 2400 closed without payment, indicating they were either (a) found to be groundless, (b) dropped by the plaintiff, or (c) decided by a jury in favor of the defense. The remaining 1,000, including 30% of the office claims, closed with indemnity payments totaling \$110 million.

Allegations in the office claims, in descending order of frequency, were as follows:

- Failure to diagnose conditions other than cancer, including myocardial infarction, fracture, appendicitis, pulmonary embolism, tuberculosis, cauda equina syndrome, brain tumor, and detached retina
- Failure to diagnose cancer
- Negligent treatment
- Negligence in the performance of a procedure, including biopsy, vasectomy, removal of a skin lesion, removal of cerumen, and laser therapy
- Negligence in the prescribing or administration of medication.

In descending order by indemnity payment, the order is as follows:

Abbreviations Used:

CBE	clinical breast examination
PCP	primary care provider

- Failure to diagnose cancer
- Failure to diagnose conditions other than cancer
- Negligence in the prescribing or administration of medication
- Negligent treatment
- Negligent prenatal care.

MEDICATION ERRORS

Following reports about the Institute of Medicine study, a great deal of attention was placed on the number of medication errors occurring in hospitals. Although the ProMutual Group data indicate that medication errors are a problem for their insured physicians in the office practice, the percentages show that the problem is not of the same magnitude as current reporting would indicate it is in the inpatient setting. Of 1085 office claims, 121 alleged negligence in the prescribing or administering of medication; 44 of these claims closed with indemnity payments totaling \$11.2 million.

Medication errors are not uncommon, no matter the setting. Almost every physician and nurse is likely to make some kind of medication error at some time. Some are attributable to haste, some to carelessness, some to oversight. Some are the responsibility of a single individual, some point up systems problems. Consider the following:

An elderly man and his wife who had already had flu shots went to their physician's office requesting the pneumovax vaccine. The task was assigned to a medical assistant. When the Medicare explanation of benefits arrived some time later, it indicated that the flu vaccine, not

pneumovax, had been given. Determining what actually had been administered proved impossible, for although one medical assistant had given the injection, another had drawn up the vaccine from an unlogged batch. Neither had documented anything.

It is possible that the error in this case concerned the checking off of the wrong box on the Medicare form. In the absence of any office systems or documentation, however, it is impossible to know.

Most medication errors do not cause lasting injury or death. A few, however, do. One recently in the news concerned a prescription for Isordil that the pharmacist read as Plendil. A lawsuit filed after the patient died resulted in a judgment of \$225,000 each against the physician and the pharmacist. Cases such as this point up the need to adhere to good systems whenever and wherever medication is prescribed or administered.⁵

The focus of concern in the office, however, needs to be different from that in the hospital. ProMutual Group's data indicate that for at least one group of physicians, 75% of closed medication claims were attributable to:

- Negligent monitoring, with particular problems arising for patients on long-term steroids and neuroleptics, and for those prescribed medications such as Coumadin and Digoxin which require the regular measuring of serum levels
- Lack of informed consent, an issue in long-term steroid usage, neuroleptics, and medications whose side effects would suggest a need for restricting activities such as driving and drinking alcohol
- Incorrect prescribing
- Incorrect dosage
- Contraindication because of allergy.

Some of the medication errors made in the office practice are attributable to the physician alone. Examples from ProMutual Group's closed files include the prescribing of Timoptic for a patient with asthma and failing to order Coumadin in the presence of a cortical infarct. Most, however, underscore an office practice's failure to develop, imple-

Inadequate follow-up was a problem in 64% of the cancer cases, with reliance on a negative mammogram when the patient presented with a palpable mass the most frequent issue.



ment, or adhere to systems such as the following:

- the use of a continuously updated flow sheet to record the patient's medications, including over-the-counter drugs and herbal preparations
- notation of the patient's allergy status, including "no known allergies" when appropriate, on a part of the chart readily visible to anyone writing or calling in a prescription or administering medication in the office
- taking care to write prescriptions accurately and legibly, avoiding the use of nonstandard abbreviations, the letter "u" instead of "units," and, where possible, decimals
- adherence to a system for scheduling blood tests for patients on medications requiring periodic serum levels
- development of a system for tracking laboratory test results
- the establishment of and adherence to office policies addressing prescription refills (for example, who can refill and how many refills can be requested before being seen), the dispensing of sample medications, and the need for informed consent before ordering such medications as chemotherapeutic agents and psychotropic drugs
- the education of patients either through verbal interchange or printed instruction sheets about side effects of their medication(s) and necessary restrictions on activities of daily living
- documentation of conversations with the patient about his/her medication.

Systems are not fail-safe. Unless and sometimes even if they are grounded in technology or dependent upon robotics, their success depends upon the same fallible humans who make medical errors. Systems, however, give a context within which it becomes more difficult to make an error.

FAILURE TO DIAGNOSE

If medication errors are, rightfully, a focus of the preventive steps now being formulated for hospitals in response to the Institute of Medicine study, it is the host of problems leading to allegations of "failure to diagnose" that require equal attention on the office practice side.

More than half, or 580, of the 1085 office claims, alleged "failure to diagnose." Allegations of "failure to diagnose cancer" accounted for 260, or almost 45% of those claims. The five next most frequent allegations, that is, failure to diagnose a fracture, myocardial infarction, appendicitis, pneumonia, and meningitis together represented less than 15% of all failure to diagnose claims.

Failure to diagnose breast cancer accounted for 37% of the cancer claims, with colorectal and lung following at 12% each. The reasons for the disproportionate number of breast cancer claims are several. They include patients' fear of developing and dying from the disease, their misperception that screening mammograms are 100% accurate, and their unrealistic belief that early detection always equals cure.⁶ They also include the fact that physicians do make errors in diagnosing breast cancer, with 13 months the average delay in diagnosis in suits alleging a delay in diagnosing breast cancer.⁷ Patients at highest risk for a failure to diagnose breast cancer are pregnant women and those included in Kern's Triad of Error, that is, young women with a self-detected breast mass and a negative mammogram.⁷ According to Morris and Pommier, only one third of patients with masses documented during pregnancy received definitive treatment within six months of finding the mass.⁷ These cases are among the most costly to close. Over a 10-year period, ProMutual Group's average indemnity payment in breast cancer cases involving pregnant women was

\$725,000. The corresponding figure for cases involving non-pregnant women was \$406,000.

Why do physicians delay in diagnosing cancer, and breast cancer in particular? An in-depth review of 116 cancer claims revealed three primary factors:

- lack of follow-up
- false assumptions
- inadequate coordination of care

LACK OF FOLLOW-UP

Inadequate follow-up was a problem in 64% of the cancer cases, with reliance on a negative mammogram when the patient presented with a palpable mass the most frequent issue. In many of these cases, the patient was reassured that “everything is fine” and instructed to return for another routine mammogram in a year. In some cases, that proved a lethal delay. With the false negative rate in mammography estimated to be up to or possibly over 20%,⁷ good clinical risk management indicates that physicians would be well advised not to rely on a negative mammogram when the patient presents with a palpable mass, but rather, to move on to the next diagnostic step, namely ultrasound, fine needle aspiration, or biopsy. Morris and Pommier suggest that only when physical exam, ultrasound, and fine needle aspiration are all negative can a palpable mass be safely followed with a repeat exam in no more than three months.⁷

Some physicians named in cancer claims made errors in clinical judgment that resulted in their not following through to a definitive diagnosis. In one colon cancer case, there was no follow-up with a patient in his 50s whose stool tested positive for blood. A patient whose PSA rose in three successive tests received neither referral, nor treatment, nor further work-up before being diagnosed with prostate cancer. Likewise, a patient whose x-ray revealed a mass at the gastroesophageal juncture received no follow-up before being diagnosed with carcinoma of the stomach.

Systems errors were more readily visible when the follow-up problem dealt with scheduling problems, including missed or cancelled appointments. In some cases, a patient who had been directed to return for a repeat mammogram

in three to six months delayed scheduling the second film for one year or, if the office practice had no system for recalling or reminding patients, for up to three years. These delays occasionally proved lethal. Some would argue that the delay in diagnosis in these cases was the responsibility of the patient. That is true, but only in part. Only in cases where the physician could demonstrate that he/she had made every reasonable attempt to follow up with an inattentive or non-compliant patient did the burden of responsibility for inadequate follow-up shift from physician to patient.

System errors were completely to blame in the breast, cervical, and lung cancer cases in which the loss or misfiling of abnormal laboratory or x-ray results led to a lack of follow-up and a delay in diagnosis. Tracking systems that include the patient's name, kind of test scheduled, date the test result is received, date the patient is notified of the result, and required follow-up can avoid this kind of error.

Many physicians are reluctant to exchange their own “individual routines, what they have found to be the most efficient and natural way to run their office”⁸ for more formal systems. ProMutual Group's files, however, are resounding testimony to the fact that routines are subject to breakdown under time pressure, changes in personnel, or accident and oversight. Systems are more secure assurances that important data will not be overlooked and timely diagnoses will not be missed.

FALSE ASSUMPTIONS

In some of the cancer claims, the problem was not an absence of systems but a false assumption. In these cases, inadequate investigations into initial complaints and concomitant inadequacies in timely follow-up resulted from the physician's hastily-made suppositions about the etiology of a symptom, his/her failure to perform a thorough diagnostic work-up, and his/her failure to include cancer in the differential diagnosis. Some of the false assumptions that were later found to be cancer were the following:

- palpable breast masses assumed to be fibrocystic disease (breast cancer)
- anemia assumed to be gastritis (meta-

static breast cancer)

- rectal bleeding assumed due to hemorrhoids (colorectal cancer)
- inguinal pain assumed due to hernia (testicular cancer)
- weight loss assumed due to depression (lung cancer)
- night sweats assumed due to menopause (lymphoma)
- sore throat assumed due to tobacco use (cancer of the tongue)

Except in a life-threatening emergency, a rush to judgment has no place in medicine. If treatment of the patients involved in the above cases had been based on an objective diagnosis rather than a subjective assumption, it is likely that fewer errors would have been made, fewer claims would have been filed, and fewer patients would have suffered and died.

Physicians interested in minimizing their risk of a claim alleging “failure to diagnose cancer” would be well-advised to perform or order all diagnostic tests that seem reasonable, to treat sparingly until a definitive diagnosis is made, to “think cancer” before ruling it out, to remain open to the possibility of cancer in a young person and to atypical presentations of cancer, and to refrain from assuring a patient a mass or lesion is benign until it is proven not to be malignant.

INADEQUATE COORDINATION OF CARE

Inadequate communication underlies many of ProMutual Group's claims, regardless of medical specialty or allegation. It is most often physician-patient communication that proves inadequate. In a number of the cancer claims, however, the problem was communication between or among the physicians involved in a patient's care. In several cases, the patient's internist failed to perform a clinical breast examination (CBE) because he/she believed the patient's gynecologist had done it. In fact, the patient was seeing the gynecologist for another problem and the CBE, initially deferred, was never done. In some cases, there was no agreement between primary care provider (PCP) and specialist about who was responsible for the ongoing management of a patient with cancer. The result was

that neither did anything. In some cases, the PCP did not share with a specialist sufficient information for the latter to perform a complete assessment. In several cases, physicians depended upon the patient to relay information to other physicians rather than contacting them themselves. And in a few cases, notably those in which a routine preoperative chest film indicated a potential lung cancer, a surgeon filed the report in the chart without notifying the PCP, saying, in essence, "It's not my responsibility." Patients usually think otherwise; so too do attorneys and juries.

DISCLOSURE

Physicians who assume responsibility both for the care they give and the errors they make are those least likely to be sued. According to one attorney, almost half of all malpractice cases might have been avoided if the physician had offered disclosure or apology in the aftermath of a medical error.⁹ However, in medicine's current "blame culture"¹⁰ in which errors aren't permitted, accidents are someone's fault and physicians are expected—and expect themselves—to be perfect, acknowledgement of one's imperfections, whether to one's self, one's patient(s), one's colleagues, or one's friends and family, can be extremely difficult. Difficult becomes all but impossible when one adds to the emotional burden of admitting error the physician's fear of professional reprisal if he/she is reported to a local or state medical board and his/her fear of financial loss if a medical error becomes a malpractice suit or media event.

No matter how difficult or how fearsome the potential repercussions for the physician, honesty with the patient and his/her family is always the higher path. It is the duty prescribed in the American College of Physicians Ethics Manual.¹¹ It is also the expectation of patients, who are likely to be far more understanding of human fallibility than of lies and cover-up. Once a suit is in process, lies and cover-up are almost always revealed in the process of discovery or intuited by a jury. In either case, the impact upon the physician is invariably negative.

Only in cases where the physician could demonstrate that he/she had made every reasonable attempt to follow up with an inattentive or non-compliant patient did the burden of responsibility for inadequate follow-up shift from physician to patient.



SUPPORTING THE PHYSICIAN

Until medical error is perceived as an opportunity for growth and change rather than an indictment of person or practice, hospitals, medical societies and malpractice insurers should determine how best to support the physicians who make errors, particularly those that result in claim and suit. Most of those who commit a medical error are good practitioners. Some are trying to do too much, often meeting patients' needs at the expense of their own. Some are trying to balance the demands of their own sense of professional ethics with the economic mandates of a health care system in flux. Some make assumptions. Some focus too narrowly. A very few believe they can do no wrong. Almost all, however, suffer when they realize that their action or inaction resulted in harm rather than healing. The shame, guilt, fear, anger, and self-recrimination many experience as the result of committing a serious medical error can lead to depression, self-abuse with drugs or addiction, or even suicide.

Making professional support available to these physicians is a mandate rather than a choice if one is sincere in the desire both to help rather than condemn medical professionals who make serious errors and to decrease this group's likelihood of making another medical error. In identifying behaviors and traits that predisposed one physician or set of physicians to involvement in an adverse outcome, support groups can also encourage other physicians to take preven-

tive rather than restorative action with respect to medical errors.

CONCLUSION

Medical error exists wherever medicine is practiced. It exists because fallible human beings work in imperfect systems. The rate of medical error, however, can be reduced to realistic, if not acceptable levels.

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Getting Ready for Skiing

Michael Belanger, MD, and William Grana, MD, MPH

As the evening weather report calls for snowstorms across Vermont, New Hampshire and Maine, an estimated 15 million Americans start to think about skiing. Skiing is an exciting and strenuous winter sport. Few experiences provide the sense of freedom and accomplishment that downhill skiing does.

Part of the thrill of skiing is the inherent risk. Certain simple measures, though, can make skiing safer. Skiers must be prepared to deal with a number of adverse environmental and behavioral conditions: e.g., sudden change in altitude, increasing activity, excess alcohol and caffeine, and inadequate hydration. Moderation and allowing sufficient time can ease acclimatization to these changes.

While on the mountain, skiers are often exposed to wind, sun and temperature extremes. Layered clothing, with a wicking layer (like polypropylene) closest to the skin and a wind-resistant outer layer, provides protection that is adjustable to rapid weather changes. Sun block combined with UV protective sunglasses or goggles are important skin and eye protection.

Skiers should know the common ski injuries. The upper extremity is often injured in falls. Thumb injuries in general and ulnar collateral ligament injuries at the base of the thumb (metacarpal-phalangeal joint) are very common. Injury to these joints accounts for 8-10% of all ski injuries. This injury occurs when the hand is placed on the snow surface with the thumb pulled outward and back on top of the ski pole grip. Older 'pistol grip' poles and certain strap techniques prevent pole release from the hand during a fall. By releasing the thumb from the pole, many such injuries are prevented. Some ulnar collateral ligament injuries will require surgical treatment. While still on a ski vacation these injuries are immobilized in a splint or a cast, which allows continued activity prior to future treatment.

Shoulder trauma accounts for 4-

11% of skiing injuries. The usual mechanism of injury is falling on the shoulder. Rotator cuff tendon tear, shoulder dislocation and acromioclavicular separation as well as clavicle fracture are common. After initial evaluation and treatment, most of these injuries will require treatment with a sling and follow-up with an orthopedist once back home. Depending upon severity, some will require surgical reconstruction.

*Racket sports like tennis
and squash emphasize
coordination skills
similar to skiing.*



Advances in equipment have helped to decrease the overall lower extremity injury rate by about 50% since the 1970s. While modern boots provide excellent protection for the foot and ankle, modern bindings have made tibial shaft fractures less common. In order to maximize the effectiveness of these advances, the boots must be in good repair without damage to the boot-binding interface. Bindings must be adjusted for the skiers' height, weight and skiing level. A certified binding technician should perform release-testing to confirm that the bindings are actually releasing at the proper loads. Each day, prior to skiing, skiers should "self-test" their bindings by stepping into the binding and then releasing it - first by twisting out of the toe piece and then leaning forward to release the heel. This safety check assures that the adjustments are roughly appropriate, and also cycles the springs inside the binding mechanism, which has been shown to encourage predictable release loads.

One unfortunate side effect of the additional protection afforded to the foot, ankle and leg has been an increase in the number of knee injuries. The forces in the past which may have led to a sprained

Abbreviations Used:

ACL	anterior cruciate ligament
UV	ultraviolet

ankle or even a tibia fracture are now more likely to create a knee ligament sprain. Knee injuries are predominantly soft tissue and comprise approximately one third of all ski injuries. Approximately one third of significant skiing knee injuries are to the anterior cruciate ligament (ACL). Surgical reconstruction is often required to obtain adequate knee stability to return to skiing. Strength and endurance in the thigh muscles may be protective of the ACL. Specifically, hamstrings strength that is equally proportioned to quadriceps strength is theoretically protective of the anterior cruciate ligament.

In the past few years there have been a number of widely publicized ski-related head injuries. Overall head and spine injuries account for less than 10% of all ski injuries. However, the results can be devastating. The usual mechanism involves high-speed collisions and falls. Helmets, previously worn only by competitive racers, have become popular among recreational skiers. Not only protective against trauma, modern helmets are also warm and comfortable.

Conditioning programs for skiing should have a few components. Cardiovascular fitness from aerobic exercise is a good starting point. Bicycle exercise is low impact, but builds quadriceps strength and endurance. Hamstring curls or other hamstrings resistive exercise should be added to balance the musculature across the knee (and protect the ACL). Leg press machines or squats build strength and power in the lower extremities as well. Most gyms have machines to strengthen the hip abductors and adductors. These muscle groups can also be strengthened with theraband or pulley resistance programs. Strong but flexible abdominal and back musculature ties the dynamically active lower extremi-

ties to the quieter rhythmic motions of the torso and upper extremities. Sit ups, crunches, leg ups and back extensions work together to provide this strength.

The arms function primarily in balance and timing of turns. The pole plant initiates a turn. After this initiation, the trailing arm with the pole provides proprioceptive feedback during the turn. Depending on the snow surface, repetitive pole plants can tax the shoulder, elbow and wrist. Lower weight, high repetition exercise combined with stretching and flexibility prepares the upper extremity for skiing motions.

The final components of ski conditioning are balance agility and coordination. Racket sports like tennis and squash emphasize coordination skills similar to skiing. Soccer is uniquely appropriate in that it focuses on very similar eye foot and leg coordination skills as well as provides excellent cardiovascular conditioning. Step aerobics that include lateral motion mimic many of the motions of skiing. Balance board or rehab ball ac-

tivities can take balance and coordination to the next level of difficulty.

Preparation makes the skiing experience not only safer, but also more fun. The first preparation to make is physical conditioning. Fitness for skiing consists of cardiovascular fitness, flexibility, strength and agility. Many "dry land" activities can help to prepare for the ski season. Time spent at home to ensure that your body and ski equipment are in good repair and appropriately adjusted makes your ski trip safer, less chaotic and more enjoyable.

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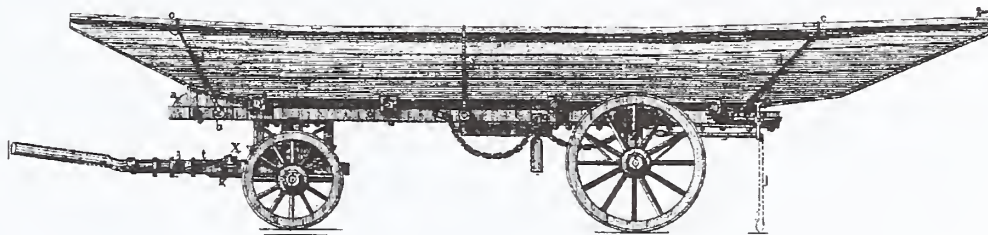
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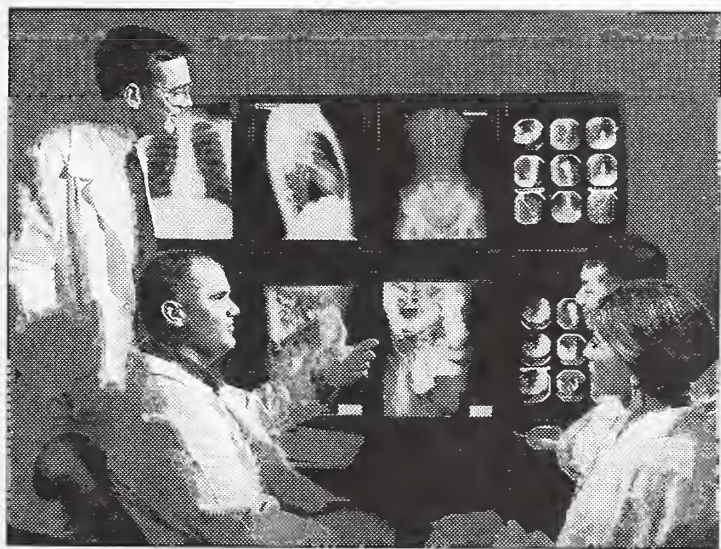
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PPS and the Physician's Role: Home Care

Cynthia Votto, RN, MS

The Rhode Island Home Care Partners Association and the Roger Williams Home Care Agency have collaborated to reach out to the physician community with information regarding the transformation of the Medicare reimbursement system that will affect Medicare home-health certified agencies across the nation.

The Balanced Budget Act of 1997 was designed to convert home health payment methodology to a Prospective Payment System that would end cost-based reimbursement and create incentives to become more efficient in the delivery of care for Medicare home health patients.

The Prospective Payment System will be implemented on October 1, 2000.

The PPS will incorporate a national 60-day episode payment, adjusted for patient condition and area wage costs, for all services provided to an eligible beneficiary under a medical home health Plan of Care. Under PPS, an agency is paid for a 60-day period of care, without regard to the amount of services or supplies it provides in a sixty-day period. Similar to the DRG payments, the agency's incentive will be to provide care more efficiently and decrease utilization. The October 1st PPS law will affect the home care billing and payment practices.

Payment for services will remain specific to the individual beneficiary (who is home bound and under a physician's Plan of Care) and to the site of the services delivered.

The fundamental physician responsibility in the PPS payment system is to determine the patient's health care

needs and advocate for the services required meeting those needs. The physician's documentation of a patient's specific health condition is the key role in meeting those needs.

Physicians have three specific responsibilities:

- Certify that the patient is confined to home and is in need of skilled care.
- Develop, certify, and recertify the Plan of Care with the key aspects of the patient's condition.
- The physician's primary diagnosis will dictate the payment for the 60-day episode (HHRG)

Any changes to the Plan of Care must be signed and dated by the beneficiary's physician within the 60-day episode. Telephone orders must be reviewed, signed and returned as soon as possible.

The Oasis tool, developed by HCFA, is a vital part to home health reimbursement. It is designed to be utilized by the nursing staff to complete an accurate assessment of the patient's physical, mental, and social conditions. The Oasis tool's 20 elements will serve as indicators of the patient's acuity level and provide HCFA with reimbursement figures.

Each initial home health agency claim must be based on a current Oasis case-mix.

The physician has always played and will continue to play a critical role in helping to assure that medical home health patients receive appropriate care.

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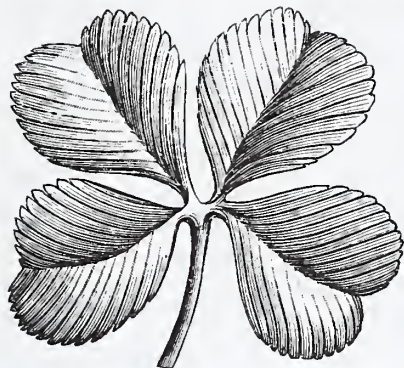
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Abbreviations Used:

HCFA	Health Care Financing Administration
HHRG	Home Health Resource Group
PPS	Prospective Payment System





Medical Myths

Ignorance is preferable to error; and he is less removed from the truth who believes nothing, than he who believes what is wrong. — THOMAS JEFFERSON, Notes on the State of Virginia



The Myth of Routine Laboratory Testing

Joseph L. Dowling, Jr., MD

[PRESENTED IN PART AT THE 678TH MEETING OF THE NEW ENGLAND OPHTHALMOLOGICAL SOCIETY, MARCH 10, 2000]

Routine laboratory testing has long been and continues to be a strict requirement before elective surgery.¹ A complete blood count (CBC), electrocardiogram, chest x-ray, serum electrolytes, blood urea nitrogen (BUN), creatinine, and serum glucose are among the most frequently required tests but there is currently little agreement as to which tests are necessary, at what age, and how recently.² The theoretical purpose of routine presurgical testing is to detect disease present in an asymptomatic patient that, left undetected, might affect the outcome of the procedure. A reasonable question then is how effective is routine testing in achieving this goal? Curiously, despite the many years that routine testing has been required, and despite the millions of tests that have been performed, the medical literature seems to contain no documentation to confirm any benefit from such testing. There are, however, numerous studies which show routine testing to be of little or no value. For recent examples, Turnbull and Buck³ reported on 2,570 otherwise healthy patients undergoing elective cholecystectomy. They reviewed the 5,000 screening tests performed on these patients and concluded they had contributed nothing to the information obtained from the history and physical examination. Kaplan et al⁴ reviewed 60,000 preoperative laboratory tests. Even with very broad indications, 41% of these tests were deemed to be not clinically indicated. They found only one significant unanticipated abnormality, an abnormality which had no effect on the outcome of the subsequent surgical procedure.

Cataract surgery is the most frequently performed surgical procedure on older Americans. Since cataract patients tend to be elderly, and to have significant coexisting medical conditions, if any group were to benefit from routine testing, it would likely be these patients. Recently Schein et al⁵ reported the results of a prospective, computer randomized, double-masked study of 19,557 cataract operations performed in 9 separate centers. Nine thousand, six hundred and twenty-four operations were preceded by laboratory testing consisting of an EKG, CBC, serum electrolytes, BUN,

If the concept of evidence-based medicine has any validity, routine laboratory testing should be promptly eliminated.



creatinine, and glucose. A comparable group of 9,626 operations were preceded by no laboratory testing. All patients were carefully followed through surgery and the postoperative period until convalescence was complete. (Table 1)

Analysis stratified according to age, sex, race, ASA risk class, and coexisting illness revealed no difference in the incidence of complications or in the outcomes of the two groups. The conclusion was clear: routine medical testing does not contribute to the safety or outcome of cataract surgery.

Aside from lack of effectiveness, routine testing has other problems, particularly reliability and interpretation. The normal range of tests which are reported in continuous numbers is determined by the mean value in a supposed normal population, plus and minus two standard

Abbreviations Used:

ASA	American Society of Anesthesiologists
BUN	blood urea nitrogen
CBC	complete blood count
EKG	electrocardiogram

Table 1. Pre-operative Laboratory Testing Before Cataract Surgery

119,557 Consecutive Cataract Patients Randomized
99,624 - Surgery Preceded By Routine Testing EKG, Cbc, Electrolytes, Bun, Creatinine, Glucose
99,626 - Surgery Preceded By No Testing
Result: No Difference In Complications Or Safety Between The Two Groups

Table 2. Linkage between number of tests and abnormal results

Tests Ordered	Likelihood of at least one Abnormal Result
1	5%
2	10%
6	26%
12	46%
20	64%

deviations. Mathematically, therefore, 5% of all test results will be false (this does not consider the possibility of laboratory error). Since each test stands on its own when multiple tests are obtained, the likelihood that a normal person will be reported as normal diminishes rapidly. (Table 2) The biological phenomenon of regression to the mean and disease prevalence also impact the reliability and interpretation of laboratory tests. For example, a patient with a positive test for a disease with a prevalence of 1% has only a 16% probability of the disease actually being present.

Binary tests also have a high incidence of false positives, but they are less easily quantified. Durbridge et al⁷ reviewed 632 routine electrocardiograms of which 101 were initially reported as abnormal. Only 4 of these abnormalities were considered significant, 2 were obvious from the medical assessment, and no cardiac complications were encountered during surgery in any of these patients. False positive test results engender additional tests, additional costs, additional referrals and often unnecessary patient anxiety.

The EKG is the most widely required and most contentious of all preoperative tests. Its purpose is purportedly to detect unrecognized ischemic heart disease, unrecognized arrhythmias, silent infarctions, and to serve as a baseline for future cardiac evaluation. A review of the available literature and clinical experience indicate that routine EKGs are neither effective in identifying these abnormalities nor in serving as baseline data.^{8,9}

Routine laboratory testing has been cited as protection against medicolegal liability. In actuality, studies show that abnormal test results, often equivocal, frequently sit in patients' records without follow up, increasing rather than decreasing legal vulnerability.¹⁰ Finally, there is the matter of cost, an issue which physicians can no longer ignore. The total annual expenditure of the health care system for preoperative laboratory testing is estimated to be approximately 30 billion dollars.⁵ It is further estimated that at least half of this could be saved by judicious ordering of tests, and an equal amount could be saved by elimination of routine testing for pre-hospital admission, and for selected groups of patients.

The purpose of this paper is to demonstrate the myth



that routine laboratory testing is useful in evaluating the preoperative patient. It is not meant to, and does not infer that patients do not need evaluation before surgery. On the contrary, numerous unrefuted studies^{3,10} show that preoperative evaluation for elective surgery is essential and best accomplished by a general medical assessment. Laboratory tests as a part of that assessment are only indicated if the patient has a new or worsening medical problem which warrants investigation on its own merits.

Much of past medical practice has been based on tradition, intuition and anecdotal experience. Currently the emergence of evidence-based medicine is leading to more effective and more rational medical practice. If the concept of evidence-based medicine has any validity, routine laboratory testing should be promptly eliminated.

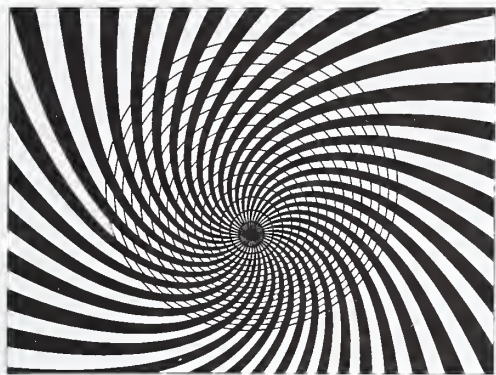
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IMAGES IN MEDICINE

Small Bowel Intussusception Due to a Lipoma

Jamie S. Stallman, MD, and William W. Mayo-Smith, MD

Abbreviations Used:

CT computed tomography

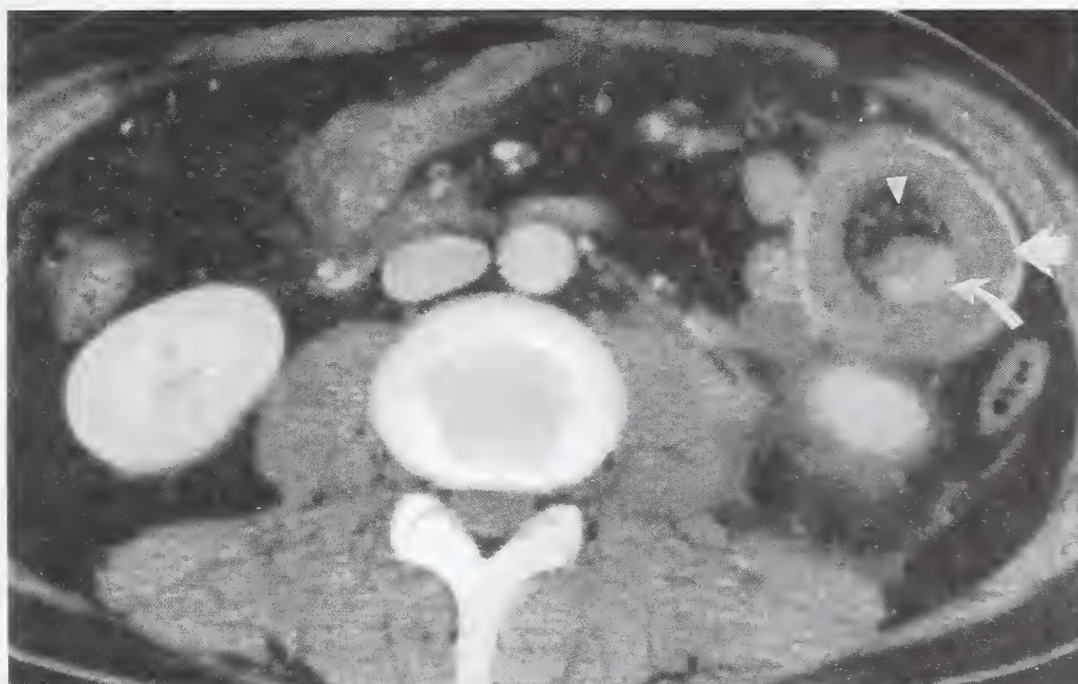


Figure 1: Axial CT scan with oral and intravenous contrast enhancement reveals the Target sign of intussusception (arrow). A loop of proximal jejunum is seen to be markedly dilated with another tubular enhancing soft tissue density structure within it (curved arrow). Low density mesenteric fat is seen between the two loops (arrow head).

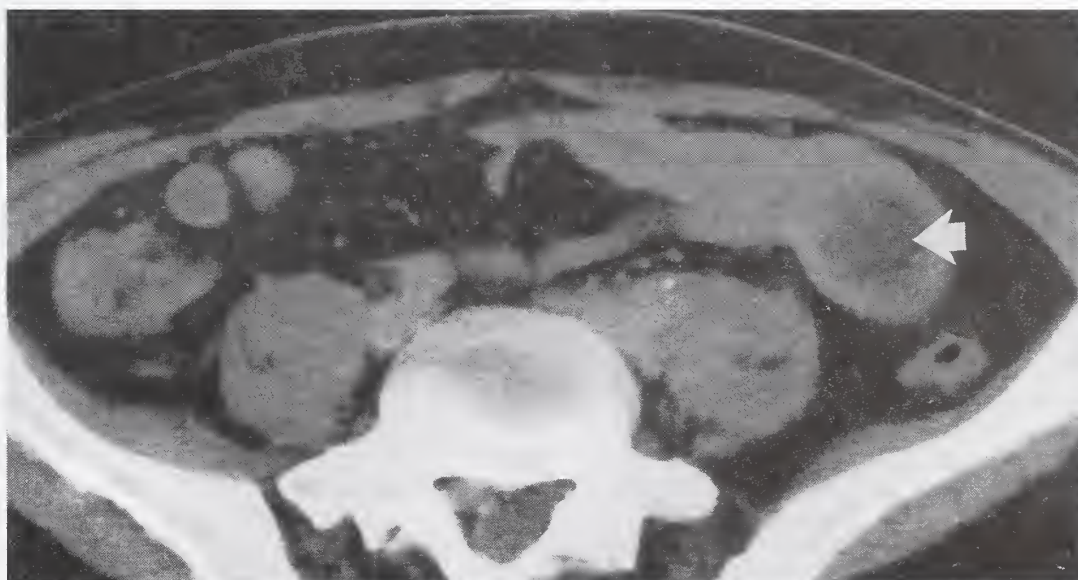


Figure 2: A lower axial image reveals the lead point of the intussusception to be an intraluminal low density mass (arrow).

Intussusception is a herniation of a bowel segment into the lumen of adjacent bowel. Common sites of intussusception are ileo-colonic, colo-colonic, and entero-enteric. The most common clinical presentation is non-specific abdominal pain. The most common age group in which intussusception occurs is the pediatric population, where

inflammation in the terminal ileum serves as a lead point. In adults, the most common etiology is a mass which can be benign or malignant. Other causes include focal inflammation and celiac sprue.

Intussusception is a difficult diagnosis to make on clinical grounds because the patients typically complain of abdominal pain that is intermittent and variable in location. In children, where ileo-colonic intussusception is by far the most common type, barium enema and ultrasound are appropriate imaging modalities. In adults with abdominal pain, CT scan with oral and intravenous contrast material provides the most information about a large array of abdominal pathology. CT findings of intussusception are specific. There is a tubular soft tissue density inside another tubular structure of the same attenuation with a rim of low density fat between the two. This is the so-called "Target sign" seen on CT. Secondary imaging features may include proximal obstruction, local mesenteric inflammatory change, bowel wall edema, free fluid, and perforation.

Intussusception can be seen in asymptomatic patients. In patients who do have abdominal complaints, untreated intussusception may lead to bowel obstruction, ischemia, and infarction. Therefore,

prompt surgical evaluation is important.

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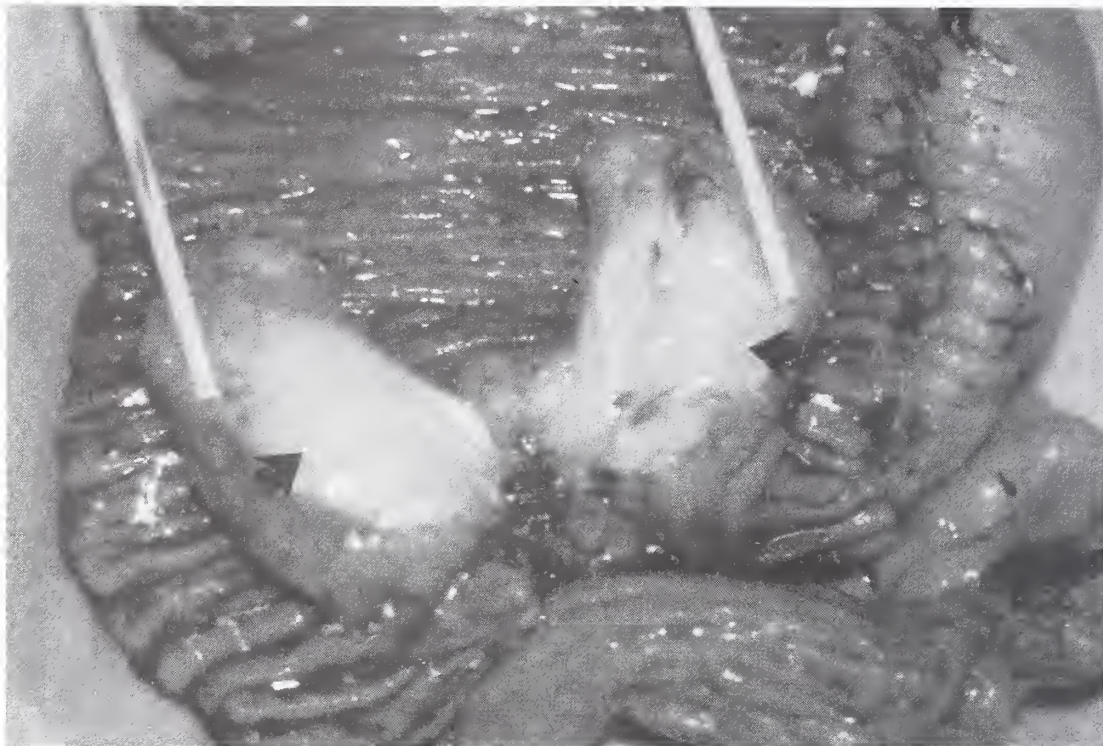


Figure 3: Gross pathologic specimen of resected jejunum reveals a bisected polypoid lipoma (arrows).

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Mammographic Screening – A Review

Arnold H. Herman, MD

Mammography is the most sensitive test for the early detection of breast cancer. The cancer found by mammography provides a lead-time of 3 to 5 years over the cancer discovered on clinical breast examination.

While this is common knowledge among the medical and lay community, the reason given by women for not obtaining a mammogram is that their physician did not request the study. As a result, many women are not screened regularly, resulting in the late diagnosis of breast cancer. It is imperative that all health care providers continue the effort to increase the number of women who obtain routine screening.

Fortunately, Rhode Island law requires all health insurers to provide mammography coverage. Uninsured women meeting certain financial guidelines can have free mammography (and Pap smears) through the Rhode Island Department of Health's Women's Cancer Screening Program. For Medicare beneficiaries, HCFA's screening mammography policy waives the Part B deductible, carries a 20% copayment and pays for screening mammograms every year for beneficiaries aged 40 or older (and one baseline mammogram for beneficiaries aged 35-29 years).

Recent innovations in breast imaging are exciting and hold much promise for future evaluation of breast problems. None provide the sensitivity and specificity as does modern film-screen mammography. Magnetic resonance imaging of the breast is extremely sensitive in demonstrating breast abnormalities but is not very specific. Its limited availability and expense preclude it from being used for general screening purposes. Digital mammography allows manipulation of the images within the computer and reduces the number of mammogram films needed for an evaluation. Unfortunately it is very expensive and not yet available in most areas.

Current recommendations for screening mammography are for an annual mammogram beginning at age 40. After much disagreement, all national groups agree with the advantages for all women over age 40. There is no longer any recommendation for screening to begin at age 35. Some confusion remains regarding the value of mammography in women under 40 or over 75. If a woman has

a first-degree relative with premenopausal breast cancer, she should obtain her baseline screening mammogram at an age 10 years younger than her relative developed breast cancer.

Mammography in the young woman is usually unrevealing because of the dense parenchyma in the younger woman. Women with a palpable mass under the age of 35 should have an ultrasound as the first procedure. Based on the ultrasonographic characteristics, the radiologist may recommend a mammogram. The purpose of a mammogram in the presence of a palpable mass is to evaluate the remaining areas of the breast, not to evaluate the palpable mass.

The increasing number of geriatric patients has stimu-

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lated discussion regarding an upper limit for screening mammography. The only controlled studies of the benefits of mammography have been in women up to age 69. There are no scientific studies of women over the age of 70 and the few attempted are not conclusive because of the small numbers evaluated. Breast cancer is usually more indolent in the elderly. Its slow growth makes it unlikely to affect the length of a woman's life unless the cancer is detected 10 years before death. Each woman over age 70 must be individually evaluated by her physician to determine if the mammography provides enough benefit to warrant the study. The presence of comorbid disease will influence this decision. Even some 90-year old women should have screening mammography.

The basic screening mammography examination consists of two x-rays of each breast. Modern mammography equipment uses less radiation for these x-rays than the breasts receive during a chest x-ray. If any abnormality is detected on the screening mammogram (performed without a radiologist's immediate review), additional x-rays are obtained, converting the examination into a diagnostic mammography.

Medicare allows a diagnostic mammography to be ordered for:

- A new breast mass
- Breast pain
- Breast swelling or induration
- Abnormal nipple retraction
- Nipple discharge
- Unexplained axillary lymphadenopathy
- Personal history of breast cancer
- Personal history of ovarian cancer
- Personal history of colon cancer
- Further evaluation of an abnormal mammography
- Metastatic carcinoma when a primary breast cancer is suspected
- Surgically proven benign breast disease



HCFA instituted the Mammography Quality Assurance Act in 1994 to standardize the quality of mammography performed. One of the requirements is for each facility to notify the patient by letter of the results of each study. This has caused much relief for many patients but has confused and stressed many others. These letters refer to the classification of the mammograms by the radiologist when the report is dictated.

This Bi-Rads system places each mammographic study into one of six categories.

- Grade 0 is an incomplete study requiring further x-rays or an ultrasound to clarify an abnormality seen.
- Grade 1 is normal and routine annual screening is recommended.
- Grade 2 is probably benign and routine annual screening is recommended.
- Grade 3 is indeterminate and follow-up x-rays/ultrasound are suggested in less than one year, usually six months. Many radiology offices will automatically schedule these follow-up examinations.
- Grade 4 is suspicious and biopsy is recommended.
- Grade 5 is cancer until proven otherwise.

Most radiology offices will contact the ordering physician directly for all Class 4 or 5 readings.

The major advances in breast cancer management and successful treatment are in large part because of the early detection provided by the increase in screening mammography. Physicians remain in the best position to educate and encourage their patients to have mammography. It is incumbent upon physicians and all health care providers to ensure that all women eligible for screening mammography will be offered the opportunity.

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The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.

Health by Numbers



Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Jay S. Buechner, PhD

Health Benefits Offered by Rhode Island Employers, 1999

Jay S. Buechner, PhD

Most working-age Americans and their dependents obtain health care coverage through employer-sponsored group health insurance. However, coverage is less than universal among employed persons; the majority of uninsured Americans between ages 18 and 64 years are employed either full-time or part-time. Thus, any effort to reduce the number of uninsured persons must include policies and incentives to bolster employer-sponsored health benefits. Data on health benefit offerings from a recent survey of Rhode Island employers are presented here.

Methods

Between September 1999 and January 2000, 1,486 Rhode Island employers provided information concerning their practices and preferences regarding employee health benefits. The survey was a self-administered mail-out/mail-back questionnaire and requested information on benefits as of June 30, 1999. The sample included firms with three or more employees at Rhode Island locations and was structured to allow comparisons between public-sector and private-sector employers and among employers grouped by number of employees (3-9, 10-24, 25-49, 50-99, and 100 or more between 272 and 302 respondents per group). Firms received up to three mailings to solicit their participation in the survey; the final mailing was accompanied by a telephone

Abbreviations Used:

CQI	Continuous Quality Improvement
HEALTH	Rhode Island Department of Health
JCAHO	Joint Commission on the Accreditation of Health Organizations
TQM	Total Quality Management

contact attempt; 51% of sampled firms responded.

The survey included: (1) factual questions about what benefits were offered and how many employees participated, (2) questions about how employers decided to offer benefits and what to offer, and (3) questions about employers' responses to hypothetical market changes and policy initiatives. This analysis presents results concerning employer patterns in offering health benefits to their employees.

Results

Overall, 79% of Rhode Island employers with three or more employees offered group health coverage to their employees as of June 30, 1999. (Figure 1) Of these, nearly all (97%) paid some or all of the premium. In the private sector, small employers were less likely (68%) to offer coverage than large employers (97-98%). Government employers of all sizes routinely offered coverage.

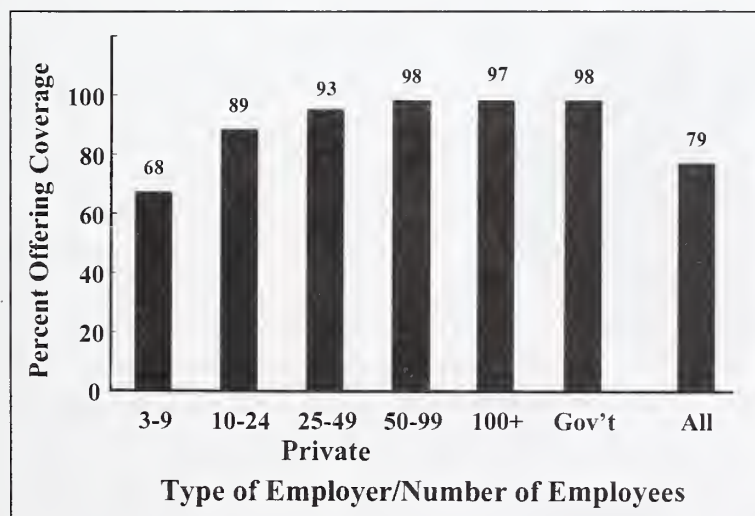


Figure 1. Employers Offering Group Health Coverage, by Type of Employer and Number of Employees, Rhode Island, 1999.

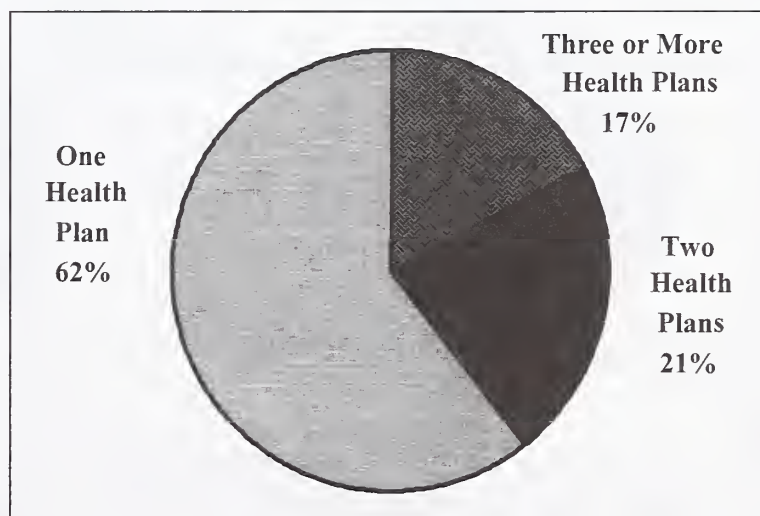


Figure 2. Number of Health Plans Offered by Employers Who Provide Group Health Coverage, Rhode Island, 1999.

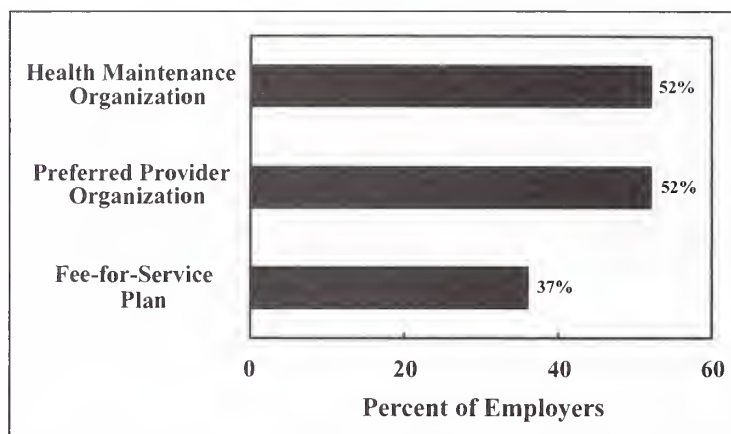


Figure 3. Types of Health Plans Offered by Employers Who Provide Group Health Coverage, Rhode Island, 1999.

When compared with data for 1999 from a national survey that included employers with between 3 and 199 employees,¹ Rhode Island employers in this range were more likely (78%) to offer health benefits than nationally (60%). This is a historical pattern; a 1993 study covering all states placed Rhode Island third in the proportion of employers offering health benefits, behind Hawaii, the only state where most employers are required by law to provide benefits, and the District of Columbia.²

The majority of employers (62%) reported offering their employees only one health plan. (Figure 2) By size, the largest employers were most likely (69%) to offer more than one plan; about one-third of the smallest employers did so.

Employers were equally likely (52%) to offer a preferred provider organization (PPO) health plan as they were to offer a health maintenance organization (HMO) health plan. (Figure 3) Just over one-third offered a traditional fee-for-service plan. (The percentages add to more than 100% because some employers offered more than one type of health plan.)

Most employers (61%) reported paying the full cost of coverage for employees who select individual (employee-only) coverage. Most of the rest paid more than half the premium. (Figure 4) Fewer employers (43%) paid the full

cost for family insurance.

Discussion

Although the 1999 survey shows that Rhode Island employers are comparatively likely to offer health benefits to their employees, there have been recent changes in the state's health care environment that may tend to erode employer offerings and employee participation. The closure of Harvard Pilgrim Health Care of New England and the withdrawal of Tufts Health Plan from the Rhode Island market in late 1999 will decrease employers' choice of insurers and may lead to higher costs as competition among insurers is reduced. Also, many employers, both nationwide and in Rhode Island, reported receiving double-digit percentage increases in their insurance premium quotes in 1999 for the first time since the early 1990s. The data presented here will serve as a baseline for monitoring the effect of these pressures on the health care coverage of Rhode Islanders.

Acknowledgement

The 1999 Survey of Rhode Island Employers on Health Insurance Coverage was funded by the Rhode Island Foundation from a grant through the Community Health in Focus Project of the Robert Wood Johnson Foundation. The support of the Rhode Island Foundation staff and advisory committee members is greatly appreciated.

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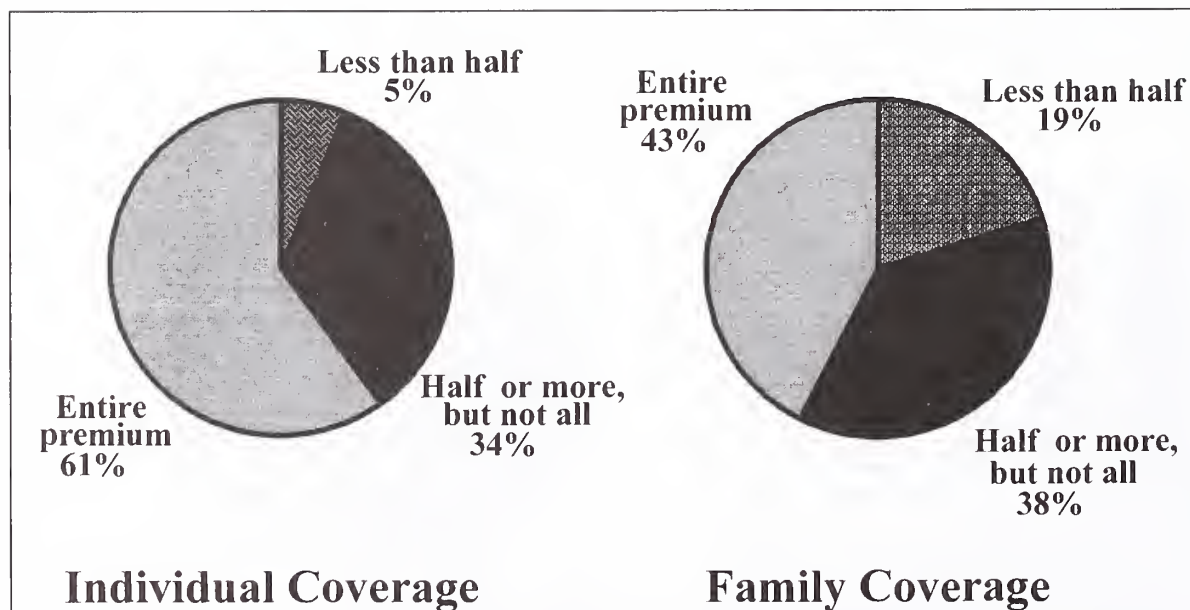
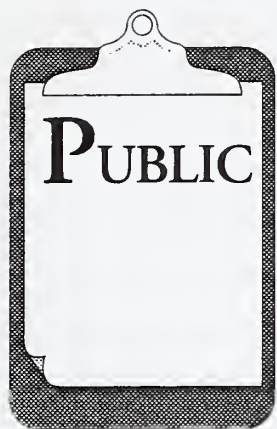


Figure 4. Employer's Share of Insurance Premium for Individual and Family Coverage, Rhode Island, 1999.



PUBLIC HEALTH BRIEFING

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by John P. Fulton, PhD

New Tobacco Clinical Practice Guidelines

Sharon L. Marable, MD, MPH

On June 27, 2000 the United States Public Health Service released the clinical practice guideline *Treating Tobacco Use and Dependence*. To cite Surgeon-General Satcher, "There has never been a better time for health professionals to help their patients break free from the deadly chronic disease known as tobacco addiction." This public health document is revolutionary because it broadens its scope beyond cigarettes to include all tobacco products. Moreover, it sets the stage for a new standard of care, where the failure of a physician to address tobacco use with a patient is considered to be extremely inappropriate.

Treating Tobacco Use and Dependence is an update to the 1996 *Smoking Cessation Clinical Practice Guideline*, which reviewed the tobacco dependence treatment literature published between 1975 and 1994. The rapid development of new tobacco dependence therapies after publication of the 1996 guideline was the catalyst for the latest guideline, which reflects a critical review of the literature published from 1975 through 1999. Consequently, 6000 scientific articles, including 3000 from the original guideline, were reviewed in order to identify a subset of articles which served as the foundation for new guideline data analyses and panel recommendations.

The *Treating Tobacco Use and Dependence* panel consisted of eighteen researchers from the private and public health sectors. Their work was supplemented by representatives from agencies such as the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, the National Cancer Institute, the National Institute on Drug Abuse, the National Heart, Lung, and Blood Institute, the Robert Wood Johnson Foundation, and the University of Wisconsin Medical School's Center for Tobacco Research and Intervention. This multi-disciplinary group identified tobacco dependence treatments and best practices proven to be effective in the scientific literature. Subsequently, the panel designed recommendations to assist clinicians in delivering effective treatments for tobacco use and dependence based on the most recently published evidence-based research. Every recommendation made by the panel was labeled with a rating that indicated the quality and quantity of research data in support of the recommendation. For instance, a recommendation was rated "A" if it was supported by multiple well designed randomized clinical trials, but "C" if

the panel reached consensus even though the results of pertinent randomized clinical trials were unavailable.

Treating Tobacco Use and Dependence is highly advanced from its predecessor. The panel reframes tobacco dependence as a treatable chronic disease, given that tobacco dependence is a long-term health problem which requires repeated intervention. The panel believes that if physicians were to view tobacco use as a chronic condition, like hypertension or diabetes, they might be more prone to provide the patient with persistent support, advice, and multiple treatment modalities to achieve abstinence. Additionally, the new guideline presents even more clinical evidence regarding the association between the intensity of tobacco cessation counseling and successful treatment outcomes. These counseling strategies (individual, group, and telephone contact are reviewed), have been proven to be consistently effective and the effectiveness increases over the course of treatment. Furthermore, the panel concludes that a physician's provision of coping skills, encouragement, and information on community-based tobacco cessation resources yields a statistically significant increase in quit rates.

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Since there are now many efficacious pharmacologic therapies for nicotine addiction, the updated guideline offers a broader range of treatment options. Bupropion SR, nicotine gum, nicotine inhaler, nicotine spray, and patch were noted as first-line medications for smoking cessation, whereas clonidine and nortriptyline were categorized as second-line medications. The panel emphasizes that tobacco addiction requires medical treatment and concludes that all smokers making a quit attempt should receive medical treatment, except in the presence of contraindications. According to the report, if physicians incorporate pharmacotherapy into their management plan, they can double or even triple their patients' abstinence rates.

Finally, the updated guideline includes strong research evidence that the medical treatments and counseling techniques outlined are very cost-effective compared to other commonly utilized medical procedures. Therefore, the panel concluded that tobacco cessation treatments should not be denied to patients when less cost-effective medical procedures are routinely delivered in the health care system.

Compared to its predecessor, *Treating Tobacco Use and Dependence* has expanded information on confronting tobacco dependence in special populations. For instance, the tobacco and pregnancy section is more robust, with examples of effective strategies to assist pregnant women in smoking cessation. The new guideline has stronger clinical evidence to support tobacco cessation interventions across different ethnic and racial minority groups. However, the panel notes that interventions should be tailored to be culturally appropriate for the specific ethnic/racial populations served. There are also new recommendations for physicians to advise parents to shield their children from environmental tobacco smoke, and to engage older smokers in smoking cessation treatment. Smokeless tobacco products are not spared from the panel's analysis. The panel recommends that smokeless/spit tobacco users should be strongly urged to quit, and should be treated with the same tobacco cessation counseling interventions recommended for smokers. Moreover, since there is clinical research evidence that dental health professionals can increase smokeless and spit tobacco quit rates, a recommendation was included for dental health clinicians to provide brief clinical interventions to all chewing tobacco and snuff users. However, at this time, there is insufficient clinical research to formally support the use of pharmacologic agents in tobacco cessation for users of non-cigarette tobacco products.

The first tobacco use cessation guideline broke ground by making a recommendation that all clinicians inquire about tobacco use at every clinical encounter. The new guideline reinforces its predecessor by outlining several brief, effective interventions which can be used in the context of a busy medical practice. It is important for the physician to *ask* the patient if she or he uses tobacco, *advise* her or him to quit, *assess* the patient's willingness to make a quit attempt, *assist* the patient in the quit attempt, and *arrange* follow-up contacts to prevent relapse. These interventions

are designed to take less than three minutes of valuable clinical time. Moreover, the patient willing to quit should receive counseling and medications to help him or her do it. On the other hand, a patient who is not ready to abstain from tobacco use should be presented with information to motivate him or her to contemplate freedom from tobacco. This may include a brief message about the impact of tobacco on the person's underlying disease or children and the benefits of quitting. These points should be consistently repeated every time a physician encounters an unmotivated patient in the office.

Finally, the panel believes that in order for all of this to be successful, it is crucial to have systemic integration of tobacco cessation policies, clinical office prompts, and appropriate financial support for treatment from tobacco dependence throughout the health care delivery system. According to the panel, medical providers need to be given the education, resources and incentives to offer consistent tobacco cessation services for their patients. All hospitals should have policies supporting tobacco cessation services on the in-patient level. The panel challenges health plans to reimburse providers for tobacco dependence treatment and to pay for all pharmacotherapy and counseling which have been proven to be effective on the basis of the panel's criteria. The panel believes that health insurance purchasers also need to demand that their policies cover the full spectrum of tobacco cessation treatment.

With the release of the new *Treating Tobacco Use and Dependence* guideline we have a window of opportunity to improve the public's health. We have the knowledge to decrease disease and deaths from tobacco addiction, and are supported by forces driving tobacco cessation policy changes within the health care system. Now is the time. We must play a strong role in helping our patients quit.

Copies of *Treating Tobacco Use and Dependence: A Clinical Practice Guideline* are available by calling the Agency for Healthcare Research and Quality at 1-800-358-9295, or by downloading the document from <http://www.surgeongeneral.gov/tobacco/default.htm>

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Sharon L. Marable, MD, MPH, is Assistant Medical Director, Division of Disease Prevention and Control, Rhode Island Department of Health, and Clinical Assistant Professor of Community Health, Brown University School of Medicine.

Information for Contributors, *Medicine & Health/Rhode Island*

Medicine & Health/Rhode Island is a peer-reviewed publication, listed in the Index Medicus. We welcome submissions in one of the following categories.

Contributions

Contributions should report on an issue of interest to clinicians in Rhode Island: new research, treatment options, collaborative interventions, review of controversies. Maximum length: 2500 words. Maximum number of references: 15. Tables, charts and figures should be camera-ready. Photographs should be black and white. Slides are not accepted.

Creative Clinician

Clinicians are invited to describe cases that defy textbook analysis. Maximum length: 1200 words. Maximum number of references: 6. Photographs, charts and figures may accompany the case.

Point of View

Readers share their perspective on any issue facing clinicians. The topic is broad (e.g., ethics, health care policy, relationships with patients). Maximum length: 1200 words.

Advances in Pharmacology

Authors discuss new treatments. Maximum length: 1200 words.

Advances in Laboratory Medicine

Authors discuss a new laboratory technique. Maximum length: 1200 words.

Medical Myths

Authors present an iconoclastic, research-based analysis of long-held tenets. Maximum length: 1200 words.

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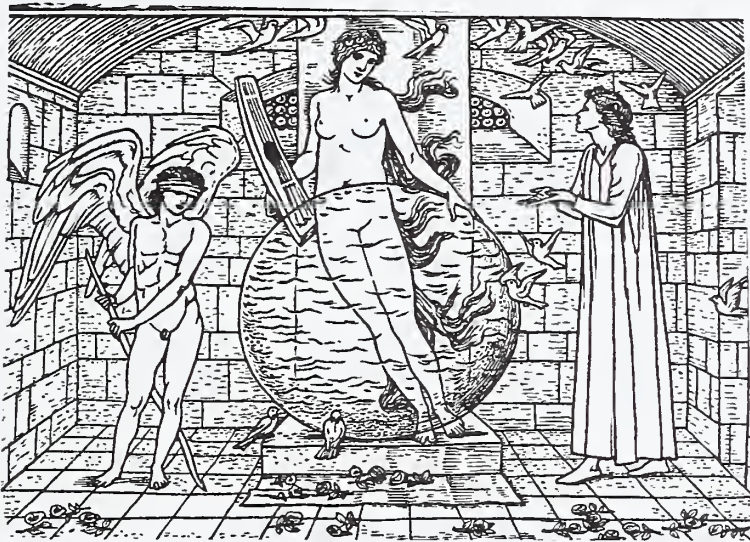
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Book Reviews

Worms, Germs and Wayward Physicians

by Stanley M. Aronson, MD
(Providence: Manisses, 2000)

reviewed by James T. McIlwain, MD

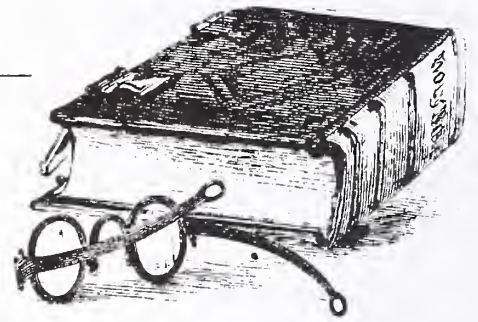
Stanley M. Aronson is Dean Emeritus of Brown University's School of Medicine, former editor of *Medicine & Health/Rhode Island*, and a regular contributor to *The Providence Journal*. From the pages of these two publications come the essays gathered in *Worms, Germs and Wayward Physicians*, as did those in *The Tapestry of Medicine*, published in 1999. The majority of the essays are historical vignettes, pages from medicine's past that have something to tell us about our profession and ourselves.

The essays in *The Tapestry of Medicine* dealt largely with institutions, founders and medical foibles, but specific disorders also received attention, particularly those related to toxins and nutritional deficiencies. Diseases, though, take center stage in this second volume and, as its title implies, the focus is on those caused by microbes and parasites. Dr. Aronson is no stranger to this subject as his interest in the nature and epidemiology of infectious disease led some years ago to the introduction of a course entitled, "The Burden of Disease in Developing Countries," which still attracts undergraduates at Brown.

Several perspectives inform the seventy-four essays presented here. Not surprisingly, some chapters highlight the technical advances contributing to the diagnosis, treatment and control of diseases. Examples include the microscope of von Leewenhoek, the antiseptic practices of Lister and Semmelweis, the vaccines of Pasteur and Jenner, the evolution of the clinical thermometer and even the key role of the lowly bedpan in the introduction of penicillin. Equal time is given to the laborious scholarship and astute observations of individual physicians who engaged in what we now call epidemiology. Thus we read of John Graunt's studies of the Bills of Mortality and the careful observations by Laveran, Ross and Manson that revealed the role of mosquitoes in the spread of disease. These chapters illustrate how progress depends as much on the advance of ideas as it does on technology.

Several essays recall the enormous historical upheavals and social disasters caused by epidemics. The deaths of up to a quarter of the population of 14th Century Europe due to bubonic plague is a well-known story, but here we are reminded of other not-so-familiar, but equally dreary, statistics. For example in the cities of early 19th Century Europe and America over a quarter of all deaths were due to tuberculosis. In 1821, puerperal fever killed 829 of the 5,139 maternity patients in Vienna's Allgemeine Krankenhaus. In 1793, 5,000 Philadelphians died of Yellow Fever between June and November. And, of course, the great influenza epidemic of 1918 killed over half a million people in the United States and 21 million worldwide.

War naturally placed soldiers at great risk for disease due



to crowding, exposure to harsh conditions and the breakdown of sanitation. Thus, during the Mexican War, seven out of eight deaths among American soldiers were due to infection of some kind. There were 20,738 cases of typhoid fever among 211,000 U.S. troops. Of 18,058 British soldiers who died in the Crimean Peninsula War, only 1,890 succumbed to enemy fire. 150,000 Serbian troops died of typhus during the first year of World War I. War clearly intensifies the problem of contagion, but, curiously, it also provides the most common metaphor for medicine's relationship to infectious disease. These wars are waged with vaccines, antibiotics and preemptive measures against agents and vectors that are the designated enemy. Yet a clear subtext of many of Dr. Aronson's essays is that the real villains are often ignorance, poverty and all those human failures that result in organized conflict.

A generous selection of essays deals with tuberculosis, which has returned to remind us that we win battles but rarely a war against a microbe. Robert Koch's discovery of the bacillus is highlighted, as are the contributions of public health measures and pasteurization to control the disease. Of equal interest, though, is Dr. Aronson's discussion of the cultural accommodation made to this illness that respected no social group. The consumptive look acquired a certain cachet among those who believed that the appearance of corporeal fragility implied heightened esthetic sensibility. Not unrelated to this is the pantheon of literary figures who had the disease, including Shelly, Keats, Byron, Robert Louis Stevenson, Chekhov, Thomas Wolfe, Thoreau, Emerson, Poe, Trollope, Goethe, Schiller, Rousseau and Samuel Johnson.

The literary theme appears also in the notice of many individuals who trained in medicine but left their marks as literary figures, among them Schiller, Chekhov and Keats, just mentioned, as well as Conan Doyle, Tobias Smollet, A.J. Cronin, John Locke, Thomas Huxley, Charles Darwin, Somerset Maugham, Mark Roget (of the thesaurus) and, had she but completed her senior year at Hopkins, Gertrude Stein. For those who find wonder in words themselves, Dr. Aronson has sprinkled philologic nuggets throughout the book. For example, we learn that botulism comes from Latin, *botulus*, sausage, that diphtheria comes from the Greek word for a piece of leather, and that smallpox is so named to distinguish it from the great pox visited on Syphilus, the shepherd who offended the Sun god in the poem by the Veronese physician Fracastoro.

Worms, Germs and Wayward Physicians is well-written and well-designed. It offers those who open its pages a rich potpourri of history, science and humanistic learning. Such a book deserves an index, but this is a minor quibble about such a good read. Thank you, Stanley Aronson.

James T. McIlwain, MD, is Fox Professor of Ophthalmology and Visual Science, Brown University School of Medicine.

Letter to the Editor:

For the past five years I've been the physician for the Rose Hawthorne Lathrop Home in Fall River, Massachusetts, overseen by the Servants of Relief for Incurable Cancer [a Dominican order of nuns]. Care at the home is free. There are no gimmicks. We accept patients from all over New England. From this experience I've learned what we surgeons can do at the end of life.

Drugs: Eliminate most of the innumerable medications that our patients accumulate which become useless in their current situation. I stop most of them on admission. A terminally ill cancer patient needs pain relief, a tranquil mind, a night's sleep and a good bowel movement. Do not underestimate the importance of the bowels. One can learn about pain control without needles from your local hospice.

Lab Tests: Not needed. Of what use is a blood ammonia in a patient

with a large liver and palpable metastases? The hospital summaries that I've read often suggest Benjamin Rush at work. Your patient may need a transfusion to replace the blood withdrawn for diagnostic purposes.

X-rays. Equally unnecessary. Your scribbled "CT Scan" on the order sheet initiates a long, unpleasant trip up and down elevators, through corridors, double doors on to a hard table and into a claustrophobic tube surrounded by scary, mysterious clicking noises and pervasive cold. The thin cotton blankets are never enough. All this to confirm what we already know. You suspect congestive heart failure. No need for chest films, EKGs or echocardiograms. Just listen to the lungs, feel for the rate and rhythm of the heart beat, look at the ankles, give a little Lanoxin and Lasix® and you are in business.

So what have we done? To satisfy our so-called intellectual curiosity, or to put together a Massachusetts General Hospital Clinical Pathological

Conference consultation, or worse, to fend off a lawsuit, we have inflicted pain and mental anguish on a dying patient who has put his life and trust in "my doctor." Plain and simple, it is cruelty in the guise of scientific study.

Finally, do not abandon your patient. Without being too sentimental, there is a special bond between a patient and his physician. So, in the final days when the chemo people, the chaplain, the radiologists, the social workers, the consultants, the myriad of do-gooders are in and out, we must continue to visit daily to justify the trust that the patient has given to us. And after discharge, keep in touch with the family.

— Frank J. Lepreau, MD
Westport, MA 02790

(Dr. Lepreau was medical director of the L'Hopital Albert Schweitzer in Haiti, 1964-1973.)



Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report

Provisional Occurrence Data
from the
Division of Vital Records

Underlying Cause of Death	Reporting Period			
	Oct. 1999	12 Months Ending with Oct. 1999		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	252	2,984	301.9	3,925.5
Malignant Neoplasms	200	2,497	252.6	6,904.5
Cerebrovascular Diseases	40	541	54.7	713.5
Injuries (Accident/Suicide/Homicide)	37	383	38.7	7,042.0
COPD	25	499	50.5	340.0

Vital Events	Reporting Period		
	April 2000	12 Months Ending with April 2000	
	Number	Number	Rates
Live Births	1,028	12,911	13.1*
Deaths	751	9,954	10.1*
Infant Deaths	(7)	(97)	7.5#
Neonatal deaths	(6)	(82)	6.4#
Marriages	464	7,832	7.9*
Divorces	197	2,666	2.7*
Induced Terminations	500	5,140	398.1#
Spontaneous Fetal Deaths	96	1,041	80.6#
Under 20 weeks gestation	(88)	(969)	75.1#
20+ weeks gestation	(5)	(72)	5.6#

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 988,480

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population

Rates per 1,000 live births

NINETY YEARS AGO

❧ [OCTOBER, 1910] ❧

In "Epithelioma," John V. Shoemaker, MD, LLD, Professor of Materia Medica, Therapeutics, Clinical Medicine and Diseases of the Skin in the Medico-Chirurgical College & Hospital of Philadelphia, described a 50 year-old tailor, born in Ireland. Most of his family had died: his father at age 70 of asthma, his mother at age 65; 2 brothers from tuberculosis (ages 56 and 29), and a sister from puerperal fever at age 21. Two brothers, 53 years old and 60 years old, were living. As a child, the patient had had smallpox, measles, pertussis. At age 21, he had a 3-month attack of inflammatory rheumatism. He had abstained from alcohol for the past 13 years, but smoked a pipe "excessively." Six weeks before coming to the hospital, he developed a tenderness in the back of his mouth, above his left nostril. Over time the growth formed a "cauliflower appearance....[that bled] when a piece of dry absorbent cotton is drawn over the surface." Dr. Shoemaker differentiated this growth from syphilitic ulcer, condylomata, and lupus vulgaris. Treatment consisted of x-rays and "application of the tincture ferric chloride," with arsenic. He predicted: "It is possible that this epithelioma may be destroyed and the patient live for many years. Yet I confess that the outlook is grave."

In "Precocity and School Life," Frederick N. Brown, MD, contrasted a child's "unexpected ripeness of thought" with a school regimen. He cautioned: "...children start school too young, spend too many hours there, have too few teachers, too little time for exercise, too sudden a transition of grades, too few playgrounds..." He concluded: "Of what profit is it to mount a mental colossus upon a physical pygmy...?"

Frank T. Fulton, MD, in "Epidemic Poliomyelitis," counted over 50 cases reported to the State Board of Health in the preceding six weeks. Citing an article in *JAMA* on the experimental reproduction in monkeys of acute poliomyelitis, he noted that a monkey with polio who recovered was immune to inoculation. As a prophylactic for health care workers, he recommended Flexner and Lewis's "fresh solution of 12 parts perhydrol in 30 parts water, for use in throat and nose."

FIFTY YEARS AGO

❧ [OCTOBER, 1950] ❧

Arthur B. Kern, MD, discussed "Cutaneous Changes Associated with Pregnancy," separating those induced by pregnancy (palmar erythema, vascular spiders, subcutaneous hemangio-endothelioma, herpes gestationis, gingival changes,

cutaneous tags) from those altered by pregnancy (neurofibromatosis, psoriasis, lupus erythematosus, cutaneous tuberculosis, syphilis).

In "Perforated Peptic Ulcer," Anthony Corvese, MD, William P. Corvese, MD, and Angelo D'Agostino, MD, reviewed 500 cases from the Surgical Service, Rhode Island Hospital, 1926 to 1947. They concluded: "...the prognosis is twice as good if surgery is performed within the first 24 hours."

The Journal reprinted a letter from President Harry Truman to the Secretary of Defense, on the amendment to the Selective Service Act of 1948 that authorized the induction of physicians. "Persons...educated...at government expensewill be called first."

TWENTY FIVE YEARS AGO

❧ [OCTOBER, 1975] ❧

In "Message from the Dean: The Brown Medical Student and the Rhode Island Community," Stanley M. Aronson, MD, cited the hypertension screening program for high-risk areas in the state, conducted in conjunction with OIC [Opportunities Industrial Center]. With the help of 33 medical students, the first screening included preliminary explanations of hypertension. When students detected hypertension, they referred the patient to his own physician or to the Neighborhood Health Center. Of the first 177 people screened, 11% were referred. Also, in the past year more than 180 students had volunteered on the wards of the Rhode Island Medical Center during a staff strike.

Edward A. Iannuccilli, MD, in "Gallstone: Concepts of Pathogenesis and Treatment," noted that, "The liver is more significant than the gallbladder in the pathogenesis of cholesterol stones."

In "The National Health Planning and Resources Development Act of 1974," John T. Tierney, Deputy Director, Department of Health, and Governor Noel's designee for implementation of the Act, explained, "The Act will coordinate planning, regulation, and development to promote economy, equal access, and quality of care." Congress had authorized more than \$1 billion over three years.

An Editorial on the "Nurse Practitioner Program in Rhode Island" praised this new program at the University of Rhode Island, funded under a two-year United States Veterans Administration grant, as "worthwhile...with a progressive objective." The concept of nurse practitioners began after World War II, to profit from the returning "medical corpsmen." Rhode Island had 14 nurse practitioners; 6 students were enrolled in the first URI class.



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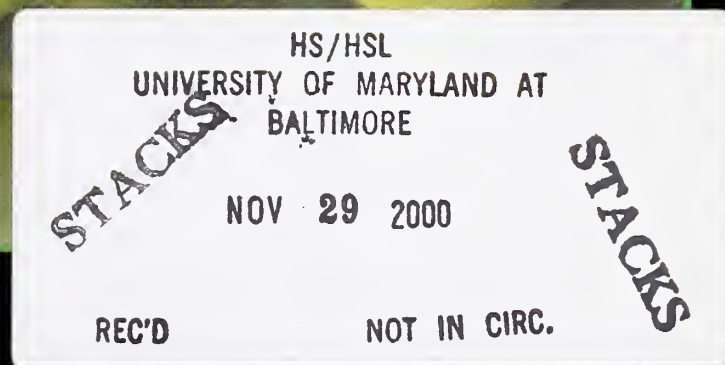
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Medical Errors



The topic of medical errors in hospitals has been in the news as a result of the National Academy of Science Institute of Medicine's report that medical malpractice caused "tens of thousands of deaths each year." The Institute recommended creation of a new federal agency to protect patients and that all health care providers report medical mistakes that lead to serious adverse outcomes. A federal "Center for Patient Safety" would spend about \$100 million per year for safety research, "just a fraction of the estimated \$8.8 billion spent each year as a result of medical mistakes." (*New York Times* 11/30/99)

I have not read the report so my speculation is based on news reports and not the actual data. I am not surprised that we doctors make lots of mistakes, but I am quite surprised that we kill so many people. I don't know if this number includes severely ill patients who probably would have died despite appropriate treatment, patients who were triaged inappropriately based on telephone consultation, and "gray" areas where errors are real but where outcome may not be truly related to an intervention or its lack. "True-true and unrelated", as we answer on the multiple-choice exam.

I have spent a fair amount of time wondering how we are supposed to re-

duce these errors. Over recent years hospitals have instituted "care maps" or "critical paths" which are often fairly detailed plans for the treatment of the more common ICD 9 codes. I hesitate to use the terms disease or disorder because not all myocardial infarcts or brain infarcts are the same despite coding. These pathways have evolved, as best I can judge, primarily to improve efficiency (i.e. reducing length of stay) but also to enhance quality. We had embraced concepts like "quality control" only to have them supplanted by "continuous quality control," "total quality improvement" and other confidence-building terms. I assume that in the future we will have "incredible quality control and unbelievably superior quality control." Having attended one quality control assessment by an outside body, I was impressed by the importance attached, as they put it, to "the paper trail" rather than to what was on the trail. Documentation seemed to be emphasized more than what was documented. Quality may not improve with documentation but lawsuits presumably are diminished.

I worry that attempts to improve quality are simply going to increase requirements for documentation and thus increased regimentation. Currently, if I don't record a certain number of required measurements in my

note, whether relevant to the patient's condition or not, I cannot file at a certain code level for Medicare. Presumably these requirements arose from quality issues so it is highly likely that such mindless issues will permeate what-

ever interventions are developed to reduce errors.

But what of existing oversights? One of the most dramatic in recent years was the re-credentialing process for specialists. I think this was a difficult step but an important one that should have been taken earlier. Has it reduced actual malpractice (not malpractice suits)? One could probably compare re-credentialed physicians to those, like myself, who have been grandfathered in, or to themselves in the year or two before they took their exams.

Required Continuing Medical Education was developed to help guarantee that physicians would remain up to date but these credits can be easily obtained without any education and often are.

I think the only ways to evaluate competency are with physician examinations and chart reviews, from panels of practicing physicians. A "one size fits all" approach such as "critical pathways" will not work and will cause more trouble than it will prevent. I wonder whether a review panel should be composed of "experts" or just competent physicians.

The main barrier to medical incompetence is the medical establishment's tolerance of our peer's failures (see my commentary, "Omerta," *Medicine & Health/RI* 1999; 82(11):382) and a hierarchy that makes it difficult for non-physicians to report malpractice without personal jeopardy. I suspect that we would do better with self-evaluation than an external board review.

— Joseph H. Friedman, MD

THE APRIL, 2000 ISSUE OF *Medicine/Health Rhode Island* was awarded Second Place in Design and Printing Excellence in the Providence Graphic Arts Association's Gallery of Printing Excellence Awards. The issue was submitted on behalf of PrintSource in the category of soft bound publications. This was one of several hundred pieces submitted in the contest.

The Morbid Fingerprints of Salmonella

There are few images more endearing than the sight of a cuddly baby chick. But, as with so many of the cuddly things of life, this one is accompanied by certain hazards. The United States Public Health Service recently issued a memorandum warning parents not to give baby chicks to their children as pets. Since many chicks are contaminated with salmonella organisms, the mere stroking of the chick may transfer the food-poisoning bacteria to the child's hands and, inevitably, to his mouth.

Daniel E. Salmon, after whom the organism had been named, was born in New Jersey in 1850. He was trained as a veterinarian, rose to be chief of the United States Bureau of Animal Industry and was instrumental in establishing a nationwide system of meat inspection. In 1885 he isolated and defined a heretofore undescribed bacterium [eventually called *Salmonella enteritidis*] from an adult male who had died following an episode of acute gastroenteritis. At that time the newly-proposed theory that germs might be causative agents of human disease was only marginally accepted. Broad segments of society expressed skepticism over such a bizarre notion. Indeed, a prominent German public health inspector, to demonstrate the absurdity of the germ theory, publicly swallowed a test-tube of Salmon's bacteria. He died within a few days following a fulminating dysentery.

Salmonella gastroenteritis is the commonest of bacterial infections of the human digestive tract. The organism is widely distributed in nature, affecting cattle, poultry, and even reptiles. In a recent poultry survey in Massachusetts, 50% of hens harbored salmonella in their digestive tracts. Even turtles are commonly infected; and baby turtles, as pets, represent yet another risk factor in transmitting salmonella.

Salmonella infection, in many, is generally of abrupt onset, causing a few days of abdominal distress, some nausea and vomiting, diarrhea perhaps, a modest degree of fever and malaise, and recovery within days. The causative agent is rarely sought since recovery is so rapid. These episodes are sometimes called intestinal flu [although unrelated to the influenza virus] or food poisoning [although true food poisoning is caused by bacterial toxins rather than by the direct action of bacteria].

In 1962, the United States Public Health Service required that salmonella infections in humans be reported. Since then the Service has documented 28,689 cases, 2,839 hospitalizations and 79 deaths caused by salmonella. The Service acknowledges that this is a gross underestimate of salmonella involvement in the health of the nation. Most epidemiologists conclude that there are a minimum of 3.8 million cases per year in the United States. In nations where food inspection standards are less rigid, the incidence rate is substantially higher; and in some developing nations it is estimated that virtually the entire population may be involved at least once per year.

Food inspectors are quire aware than even temporary lapses in hygienic procedures within food factories may lead to massive outbreaks. In 1985, for example, the level of heat necessary for pasteurization in a midwest milk plant was inadvertently lowered, resulting in 197,000 cases of salmonella gastroenteritis.

In the last few years the Public Health Service has documented major outbreaks in virtually every region of the nation.

In October 1997, a luncheon serving undercooked lasagna resulted in 75 cases of salmonella gastroenteritis. Cultures of the leftover lasagna yielded the organism. The company preparing

Abbreviations Used:

AIDS	acquired immune deficiency syndrome
HIV	human immunodeficiency virus
OCP	Onchocerciasis Control Programme
WHO	World Health Organization

the lasagna used raw eggs in the preparation of the dish. A traceback investigation showed that many of the poultry houses providing eggs were grossly contaminated with salmonella organisms.

In November 1997, 91 persons took ill after eating broccoli with hollandaise sauce in a Las Vegas restaurant. The sauce used eggs cooked at a temperature inadequate to kill salmonella organisms.

In July 1998, 58 persons took acutely ill after eating *chiles rellenos* in a Maricopa County, Arizona, restaurant. The sauce was made from raw egg batter and cheese.

There has now been sufficient experience with salmonella infection to offer some generalizations: Adults are generally the victims in instances of acute outbreaks when many are exposed to a single source of infection such as the highly publicized instances cited above. But the majority of cases in this country involve no more than one or two humans at a time; and in such settings, children are the customary victims. Indeed, the greatest risk of contracting salmonella gastroenteritis is found in children below the age of five who have not yet adopted basic hygienic standards such as the washing of hands prior to meals.

Others at high risk for salmonella infection include nursing home residents, infants in hospital nurseries, people with immunodeficiency diseases [such as AIDS] and those with certain illnesses such as leukemia or sickle cell anemia which may impair the immune defenses of the body. The outbreaks in nursing homes for the elderly have been traced not only to unhygienic kitchen practices but also to medical instruments, such as clinical thermometers, shared by many residents.

Salmonella infection demonstrates a consistent seasonal pattern: highest during the July to November interval and lowest during the February to April interval. There are some regional differences in rates but public health physicians relate this more to the intensity of surveillance. In general, rates are higher in more impoverished regions; and higher too in women, largely because of their greater involvement in food preparation. Amongst occupations, those employed as food handlers or abattoir workers are at highest risk [for themselves and their families].

Eggs remain the single greatest source of salmonella infection [82% of all cases]. Egg shell exteriors are often soiled by chicken manure; but in addition, hens infected with salmonella may pass the bacteria through their ovaries, thus contaminating their eggs before they are even laid. Raw or inadequately cooked eggs, especially in such preparations as custards, egg nogs, sauces, cake mixes and quiches have been repeatedly incriminated.

Strict standards in commercial and domestic food preparation combined with scrupulous personal hygiene remain the most effective barriers to salmonella infection. Nor is this some recent Public Health Service epiphany. Three millennia ago the psalmist asked who shall ascend the holy mountain; and the answer to his rhetorical question: "He that hath clean hands."

— Stanley M. Aronson, MD, MPH

Introduction

Charles B. Eaton, MD, and Kim M. Gans, PhD, MPH, LDN

Five out of the 10 leading causes of preventable death are nutrition-related, including coronary heart disease, stroke, several cancers, diabetes mellitus, hypertension, and obesity. Despite this fact, most physicians and health providers report being inadequately trained in nutrition. The Brown University School of Medicine has received a Nutrition Academic Award from the Heart, Lung, and Blood Institute of the National Institutes of Health (NIH) with Drs. Charles B. Eaton and Kim Gans as principal investigators. The goal of this project is to serve as a catalyst for the development, implementation and evaluation of an innovative nutrition education curriculum at the School of Medicine, its primary care residencies, and with practicing physicians. A Nutrition Education Advisory Panel (NEAP), with representatives from the Departments of Family Medicine, Pediatrics, Medicine, Community Health, Psychiatry, and Surgery at Brown University School of Medicine; Departments of Pharmacy, Nursing, Nutrition and Exercise Science at the University of Rhode Island, the Johnson and Wales Culinary Institute, the Rhode Island Dietetic Association and the Rhode Island Department of Health, is working to evaluate and revise the educational curriculum, foster joint research and training efforts, and

sponsor CME programs. This special CME edition of the *Medicine & Health/Rhode Island* is a product of this joint effort. With the increasing rate of obesity found in the United States, many patients are asking providers about the success of fad diets. In "Atkins to Zone: The Truth about High Fat, High Protein Diets," Kevin Vigilante, MD, MPH, and Mary Flynn, PhD, RD, discuss the scientific basis behind these diets' short-term weight loss and long-term deleterious effects. In "Cardiovascular Disease and Nutrition," Charles B. Eaton, MD, and Kim M. Gans, PhD, MPH, LDN, review the evidence for the diet-heart hypothesis including discussions of cholesterol, saturated fats, transfatty acids, omega 3 fatty acids, fiber, soy, antioxidants and B vitamins. Data demonstrating the clinical variability of responses to diets and the effects of total calories consumed are discussed to explain the apparent paradox found in clinical practice compared to published randomized dietary trials. Herbs and dietary supplements are emerging as important in the care of patients; their use has increased exponentially. Dorothy DeLessio, MS, RD, and Anne Hume, PharmD, BCPS, offer principles to evaluate these products, as well as web sites and resources to share with patients. Christine M. Hardy, MS, RD, LDN, and Randal Rockney,

Abbreviations Used:

NEAP	Nutrition Education Advisory Panel
NIH	National Institutes of Health

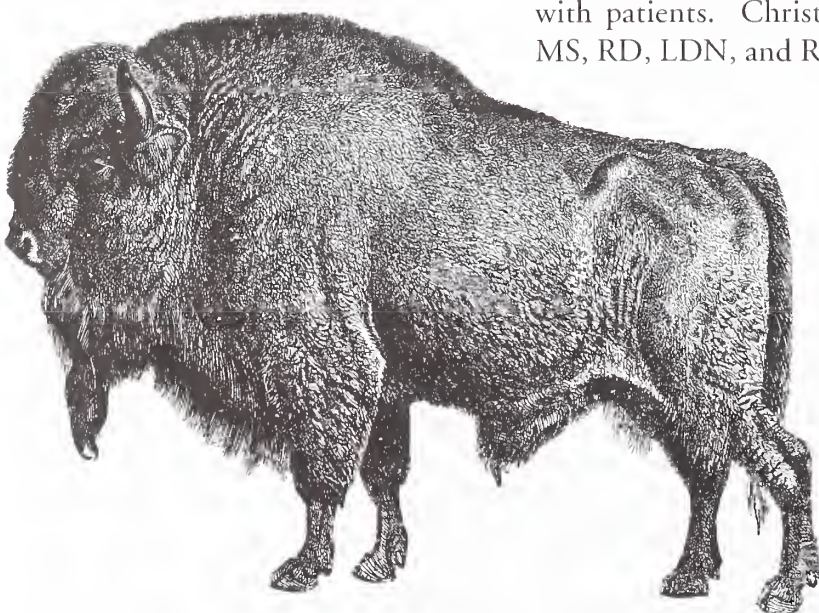
MD, describe "The Role of Fiber in the Diets of Children," providing information on both the scientific basis and practical tips for parents and children on incorporating more fiber into a diet. Finally, having knowledge regarding nutrition or access to such knowledge is only half the battle. The other half is using this knowledge to counsel patients regarding nutrition. Since over 80% of the population visits a health provider on a yearly basis, fitting nutrition counseling into every day clinical practice is important to preventing or treating cardiovascular disease, cancer, diabetes, hypertension, dyslipidemia and obesity. Christopher Sciamanna, MD, Kim M. Gans, PhD, MPH, LDN, and Michael G. Goldstein, MD, review patient-centered counseling techniques, using the 5 As: Addressing the issue, Assessing, Advising, Assisting and Arranging follow-up. Excellent resources for both health providers and patients both in paper and web-based are made available in this article. We hope you find this edition helpful to your continuing medical education needs.

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From Atkins to Zone: The Truth About High-Fat, High-Protein Diets for Weight Loss

Kevin C. Vigilante, MD, MPH, and Mary M. Flynn, PhD, RD

High fat, high protein (HFHP) diets were first introduced in the United States in the 1960s. These diets wax and wane in popularity, and the media has recently popularized several (Atkins, Zone, Sugar Busters, and Protein Power). While HFHP diets vary slightly in the foods allowed, they all restrict food sources of carbohydrates and emphasize fat and protein. HFHP diets promise the dieter weight loss despite the consumption of "unlimited" amounts of foods that are high in fat and/or protein, while severely limiting or excluding carbohydrate. The promoters of these diets mistakenly present fat and protein calories as benign and state that carbohydrate calories alone are responsible for weight gain. The HFHP content of these diets tends to make them high in saturated fat and animal protein.

There are few scientific studies published that test the efficacy of these diets for weight loss or the effect of HFHP diets on health outcomes. We will examine the potential adverse health effects of these diets using a case study.

CASE STUDY

LaRosa et al¹ examined the typical response for women on a HFHP diet. The following case is derived from that study. A woman weighing 96.7 kg initiates a HFHP diet. Prior to beginning the diet, her blood lipids (mg/dl): total cholesterol (TC) 201, low-density lipoprotein-cholesterol (LDL-c) 119, high density lipoprotein-cholesterol (HDL-c) 64 and her triglycerides: 98. After 8 weeks on the diet, she lost 6.9 kg. Having reached her goal, she stopped the diet and resumed her regular diet. At the conclusion of the diet period, her blood lipids were as follows (mg/dl: TC 229, LDL-c 158, HDL-c 57 and triglycerides 72).

Why did this woman lose weight?

Proponents of HFHP diets would claim that she reduced her insulin secretion, which in turn inhibited the activity of lipoprotein lipase (LPL) at the adipose cell. They claim this would make it dif-

ficult or impossible for lipid to be stored in the adipose tissue and weight loss ensues. However, this is unlikely to be true. The best published studies that examine weight loss using diets with varying proportions of fat and carbohydrate^{2,3} have found that weight loss was dependent on total calories consumed and not diet composition (i.e., percent of fat, carbohydrate or protein).

The HFHP diet leads to weight loss due to the decrease in energy from this diet. The American diet is approximately 50% carbohydrate. After restricting carbohydrate, it is difficult to completely compensate for the eliminated energy by eating more fat and protein. Furthermore, as both dietary fat and protein promote satiety more than carbohydrate, the dieter can restrict calories without experiencing significant hunger over the short term. Studies of HFHP diets that have measured calories have found that total calories are reduced on HFHP diets compared to diets with carbohydrate energy and that weight loss is proportional to the total energy decrease.⁴ The elimination of carbohydrate also causes the body to deplete the glycogen stores. This leads to an immediate weight loss of approximately 2-3 pounds because of the obligate water loss when glycogen is depleted. This initial one-time weight loss may be enough to "hook" patients on the diet.

Dr. Atkins's version of the HFHP diet seeks to drive the patient into ketosis. In addition to the obligate water loss from glycogen depletion, the ketotic state results in an osmotic loss of body water which is reflected as "weight loss".⁵ Like dietary fat and protein, ketosis also suppresses the appetite thus contributing to the lack of hunger.¹

INFLUENCE ON BLOOD LIPIDS

Active weight loss generally produces a reduction in LDL-cholesterol, yet this woman's LDL-cholesterol significantly increased despite a 6.9 kg weight loss. This may be explained by the saturated fat content of the HFHP diet. The

Abbreviations Used:

HDL-c	high-density lipoprotein cholesterol
HFHP	high fat, high protein
LPL	lipoprotein lipase

increase in LDL-cholesterol despite weight loss may have resulted from the unrestricted amounts of saturated fat allowed by the Dr. Atkins's diet. The decrease in high-density lipoprotein cholesterol (HDL-c) would be expected with active weight loss.

Despite studies showing a tendency of lipid profiles to worsen on HFHP diets, there are persistent anecdotal reports of improved blood lipids on HFHP diet. While counterintuitive, this is possible if the amount of weight loss is large. In some individuals, large amounts of weight loss will override the effects of saturated fat on serum cholesterol and improve the lipid profile.

However, even if blood lipids improve with HFHP diet, it is not clear that cardiac risk is reduced. The ketosis associated with some HFHP diets may increase LDL oxidation of LDL-c by 70 to 80%.⁶ This is important because it is oxidized LDL-c that is associated with coronary heart disease.⁷ Besides the potential adverse lipid changes, meat consumption itself has been related to an increase risk of coronary heart disease.⁸ Some have attributed this association of meat consumption with coronary heart disease risk to the high methionine content in meat and a subsequent increase in homocysteine.⁹

OTHER RISKS

The high meat content typical of HFHP diets is also a concern for cancer risk. High meat consumption has been shown to increase the risk of colon, prostate and breast cancer.⁹ There are several mechanisms by which meat may promote cancer. One is the production of heterocyclic amines from the searing of meat protein. Others are the iron content of

meat, which could promote oxidation, and the nitrate content of processed meat.⁹

HFHP diets consumed over time may also increase the risk of osteoporosis. The consumption of animal protein in excess of need increases urinary calcium excretion because calcium is used as a buffer in the metabolism of animal protein.¹⁰ It has been estimated that for every gram of protein consumed in excess of need, there is an approximate 1 mg increase in urinary calcium excretion.¹⁰

The HFHP diet limits fruit and vegetable consumption. Even if not strictly prescribed, the emphasis on meat may have a substitution effect, which displaces fruits and vegetables. Numerous studies have correlated increased fruit and vegetable consumption with decreasing cancer risk. Plant-based phytochemicals have been shown in vitro and in animal models to have properties that potentially lower the risk of heart disease and cancer. While human studies of the health benefits of phytochemicals are limited, the phytochemicals in plant products may explain why a plant-based diet is associated with lower risk of several chronic diseases.

An additional risk of HFHP diets is the risk of weight cycling. Most individuals are not able to sustain themselves long term on a high fat, high protein diet and thus will give up this diet and regain the weight. Several epidemiology studies have shown that weight loss and weight gain contributes to obesity over the long term and that weight cycling patients are worse off than those with stable weights even if overweight.

Lastly, these diets have created a

great deal of confusion by spreading the misconception that caloric intake does not matter. The truth is nothing matters more than calories when it comes to weight loss and weight gain.

Like all fad diets, HFHP diets are prone to failure over the long-term.



CONCLUSION

If HFHP diets lead to reduced caloric intake, they may be helpful in inducing short-term weight loss. However, often the problem with obesity is not losing weight, but maintaining the loss. Like all fad diets, HFHP diets are prone to failure over the long-term. If patients stay on an HFHP diet long term, it may predispose them to an increased risk of heart disease, certain cancers and osteoporosis.

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Table 1. Recommended Professional and Patient Resources for Weight Loss

- American Obesity Association (www.obesity.org/)
- Food and Nutrition Information Center (www.nal.usda.gov/fnic/); resource list for consumers (www.nal.usda.gov/fnic/pubs/bibs/topics/weight/consumer.html)
- National Heart Lung and Blood Institute, Resources for professionals (www.nhlbi.nih.gov/health/prof/heart/index.htm#obesity), Obesity Education Initiative (www.nhlbi.nih.gov/about/oei/index.htm), NHLBI Information Center Web site (www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/index.htm)
- Cyberdiet (www.cyberdiet.com/)
- Partnership for Healthy Weight Management (www.consumer.gov/weightloss/setgoals.htm)
- Shape Up America! (www.shapeup.org/)
- Healthy Weight Network (www.healthyweight.net/)
- The American Heart Association Declares War on Fad Diets (www.americanheart.org/Health/Risk_Factors/Overweight/Fad_Diets/index.html)
- North American Association for the Study of Obesity (www.naaso.org)
- Weight Control Information Network (www.niddk.nih.gov/health/nutrit/pubs/health.htm)

Cardiovascular Disease and Nutrition

Charles B. Eaton, MD, and Kim M. Gans, PhD, MPH, LDN

Cardiovascular disease (CVD) remains the leading cause of death in the United States, with more than \$100 billion dollars spent annually for treatment. Diet plays an important role in the etiology of atherosclerosis and contributes to the lethality of stroke, heart attack and unstable coronary syndromes. It does this through multiple mechanisms, including a direct effect on atherosclerosis and thrombosis, triggering plaque rupture and through modifying risk factors such as blood cholesterol, obesity, hypertension, diabetes mellitus. Diet plays an important role not only in CVD but also in the prevention of five of the other ten leading causes of death.¹ For these reasons, it is recommended that most non-acute patient encounters should have some time devoted to diet assessment and nutrition counseling.²

Recent studies show that the majority of primary care physicians (72%)³ consider nutrition education of patients their responsibility, but it is unclear how often this responsibility turns into action. The frequency of nutritional counseling in the primary care encounters ranges from 20% -80%.^{2,3} When nutrition counseling does occur, physicians reported spending an average of 3-5 minutes. Barriers to effective counseling included 62% with a deficit of nutrition knowledge, 67% with a lack of training in counseling skills and 50% questioned the benefits of counseling in changing patient behavior.²

The purpose of this article is to fill the knowledge deficit regarding the role of diet in preventing and treating CVD. In this article we review the scientific evidence regarding the benefits of diet modification in reducing CVD; describe the potential mechanism of action of specific nutrients that help explain the clinical trial evidence; discuss emerging consensus regarding the roles of fiber, soy, phytoestrogens, B vitamins and folate, antioxidants, alcohol and CVD prevention; and explain some

apparent clinical paradoxes in the effectiveness of nutritional therapy. Armed with this information, physicians should be able to advise and counsel patients more successfully.

DIET AND CORONARY HEART DISEASE (CHD)

Table 1 lists the primary and secondary CHD dietary intervention trials that conclusively demonstrate that a patient's diet has important, clinically relevant effects on CHD morbidity and mortality.

The above evidence, in conjunction with cross-sectional epidemiologic

Abbreviations Used:

CHD	coronary heart disease
CVD	cardiovascular disease
RCT	randomized controlled trial

studies such as the Seven Countries Study, transmigration studies such as the Ni-Hon-San study and prospective cohort studies such as Western Electric, Ireland-Boston-Diet Study, and the Honolulu Heart all demonstrate the important role of diet in preventing CVD. (References available from authors). Attempting to quantify this effect, it appears that most low fat dietary

Table 1 Randomized Trials of Diet and Coronary Heart Disease

Study	Participants	Design	Intervention	Cholesterol	CHD	Comments
Primary Prevention						
VA Domiciliary Los Angeles 1968	424 men	RCT 8 yrs follow-up	Low sat'd fat, low chol, high P/S ratio	13% decrease*	23% decrease*	Institutional setting
Medical Research Council Soybean Oil Study 1968	293 men	RCT 4yrs follow-up	low sat'd fat, high soybean oil	13% decrease*	18% decrease*	
MRFIT 1976	12,866 men	RCT 7 yrs follow-up	<10% sat'd fat, <300 mg chol	7.5% decrease	7% nonfatal MI* 7% fatal CHD*	Multifactorial greatest benefit in those who lost weight
Oslo Diet Heart 1981	1232 men	RCT 5 yrs follow-up	8.2% sat'd fat, 7.2% polysat'd, 289 mg chol	13% decrease*	47% decrease*	smoking cessation as well
Finnish Mental Health 1972	4,178 men 6,434 women	Cross over trial 6 yrs follow-up	low sat'd fat, low chol, high P/S ratio	12% decrease	18% decrease men*; 34% decrease in women (NS)	Institutional setting
Secondary Prevention						
STARS 1992	90 men with angina or MI	RCT- UC, diet, diet + cholestyramine 39 months follow-up	27% fat, 8-10% sat'd fat, 8% omega 6 and 3 fatty acids	14.2% decrease*	22% decrease CVD*	3 arm angiographic trial
DART 1989	2033 men MI	RCT- Factorial design 2 yrs follow-up	low fat, high fatty fish, high cereal fiber	No change	29% decrease in IHD deaths* but not nonfatal events in fish group	Benefit attributed to fish and fiber, and not low fat group
Indian Diet Heart Study 1992	406 men and women MI	Single blinded RCT 1 yr follow-up	Diet A= low fat, 400 gm/qd fruits, veg, nuts, soy, reinforced Diet B= low fat only, not reinforced	13% decrease*	40% decrease in cardiac events* and 45% decrease in total mortality	Better results in those patients that lost >0.5 kg.
Lyon Diet Heart Study 1999	605 men and women MI	RCT- single blind, Mediterranean vs NCEP 1 diet 4 yrs follow-up	Mediterranean diet- <35% fat, <10% sat'd fat, <4% linoleic acid, >0.6% alpha linolenic acid	No change	72% decrease in cardiac death and nonfatal MI*	Benefits of Mediterranean diet may be related to stabilization of membranes, prevention of arrhythmias & platelet inhibition.

*statistically significant.

regimens studied lowered total blood cholesterol by 12-15% with a 12-24% reduction in CHD events. An equally important finding was that diets high in fish (omega 3) and monounsaturated fats had beneficial effects with little to no effect on cholesterol values.

MECHANISMS OF ACTION

The role of fats and their constituent fatty acids have been well studied, and can best be understood by breaking fats into:

- saturated fats (lauric, myristic, palmitic, and stearic acids) found in dairy products, palm and coconut oils, and meats;
- monounsaturated fats (oleic, erucic, palmitoleic acid) found mainly in olive and Canola oils; avocados, and peanuts;
- omega-6 polyunsaturated fats (linoleic, arachidonic acid) found in most other vegetable oils, seeds, most nuts, grains; and
- omega-3 polyunsaturated fats (linolenic, eicosapentanoic, docosahexanoic) found in fatty fish, marine plants, and green leaves.

Trans fatty acids such as elaidic acid do not naturally occur in nature and are the product of hydrogenation of oils to make margarine and shortening. They are found in many fried foods, commercial baked goods, and processed peanut butter as well.

Table 2 lists the mechanisms of actions of the different types of fat.

Thus, there are well formulated pathophysiologic mechanisms to ex-

plain the clinical trial evidence regarding the diet-cholesterol-CVD hypothesis.

OTHER IMPORTANT DIETARY FACTORS

Fiber

Multiple epidemiologic studies have shown that diets high in fiber are associated with lower risk of CVD. Clinical trial evidence has been increasing. Most recently, a meta-analysis of 67 controlled trials was performed that showed that soluble fiber intake of 2-10 g/d was associated with a small but statistically significant reduction in total and LDL cholesterol of 1 to 1.3 mg/dl.⁴ These small changes may have important public health benefits, but demonstrate the modest clinical benefits of fiber in lowering cholesterol. The equivalent of three servings of oatmeal a day would on average only lower total cholesterol 1-2 mg/dl. However some patients may be more responsive, and fiber has shown to be effective in reducing obesity by replacing fat calories yet retaining satiety.

B-vitamins and folate

A diet rich in fortified cereals, vegetables and legumes, which are an excellent source of B vitamins and folate appears prudent. Recent studies have shown the important role of elevated levels of homocysteine in increasing the risk of CVD.⁵ Homocysteine is a sulfur-containing amino acid that appears to be toxic to endothelium and stimulates smooth muscle proliferation which

probably explains this association. Biochemically, homocysteine metabolism is controlled by enzymes that are in turn under the control of co-factors, including the B-vitamins B-6, B-12 and folate. Epidemiologic studies have demonstrated that diets with low levels of folate and B vitamins are associated with increased risk of CVD. Additionally clinical trial evidence has shown that supplemental folate and to a lesser extent vitamin B-6 in human volunteers lowers homocysteine levels. Definitive clinical trials evaluating whether lowering homocysteine levels through folate and B vitamin supplementation will reduce CHD are ongoing and no definitive recommendations regarding folate and supplemental B vitamin therapy are presently advocated. For patients with inadequate folate in their diet such as patients on low calorie diets or the elderly, physicians may consider 400 ug folate supplementation along with oral B12 supplementation. For patients with renal insufficiency, physicians should consider 5-15 mg of folic acid daily. For patients with premature CHD, measurement of homocysteine levels and treatment with supplemental folate, if elevated, may be appropriate in selected cases while definitive evidence is pending.

Soy Protein

A meta-analysis of 38 controlled clinical trials with diets averaging 47 g per day of soy, was associated with a 23.2 mg/dl or 9.3% reduction in total cholesterol, and a 21.7 mg/dl or 12.9% reduction in LDL cholesterol, 13.3 mg/dl or 10.5% reduction in triglycerides and with little change in HDL concentration.⁶ Large amounts of soy are found in Asian diets with common sources being soy milk and tofu. The mechanism of action of soy protein on cholesterol is unclear although it does appear to effect LDL receptor activity and VLDL Apo B turnover. Part of its effect may be due to phytoestrogens found in soy protein that have weak estrogenic effects, which may affect hepatic triglyceride lipase activity. There is some evidence that soy protein reduces LDL oxidation as well.

Table 2 Fatty acids mechanisms on lipoproteins & CVD physiology

Mechanism	Saturated Fat	Monounsaturated Fat	Polyunsaturated n-6	Polyunsaturated n-3	Trans fatty acids
Membrane Fluidity	↓	0	↑	↑	↓
LDL receptor activity	↓	0	↑	↑	↓
LDL clearance	↓	0	↑	↑	↓
LDL	↑	0	↓	↓	↑
HDL	↑	0	↓	↓	↓
Trig	0	0	↓	↓↓	0
Conduction system stability	0	0	0	↑	0
Oxidation	0	0	↑	↑	0

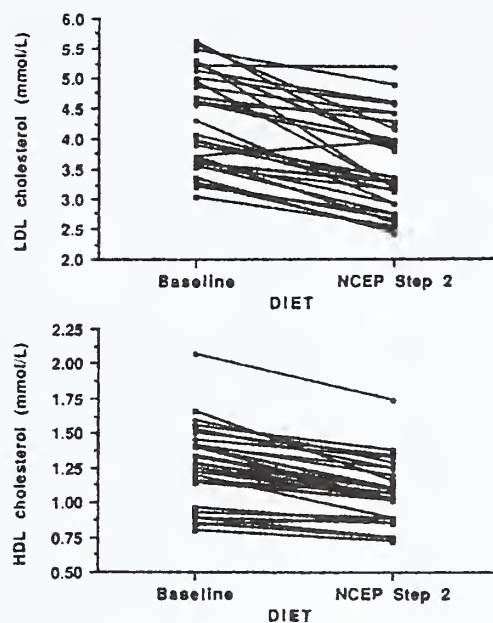


FIG 1. Plots show individual changes in LDL cholesterol and HDL cholesterol levels in men (■) and women (●) on the National Cholesterol Education Program Step 2 diet, compared with the baseline diet (n=32).

Phytoestrogens

Phytoestrogens represent a family of plant compounds that have estrogenic and antiestrogenic properties. Over 300 hundred plants have been shown to have significant amounts of phytoestrogens. Phytoestrogens can be broken into two main categories: isoflavones and lignans. Soy products are the main source of isoflavones and flaxseed lignans. The scientific evidence for the benefits of phytoestrogen are limited but fairly consistent.⁷ Asian populations which have low rates of CVD also have diets rich in phytoestrogens. Humans with diets high in phytoestrogens have high urinary levels of metabolites with estrogenic properties. Clinical trials noted above suggest that soy has cholesterol-lowering effects. Well-designed clinical trials need to be performed before any definitive statements can be made about the benefits of phytoestrogens on CVD.

Antioxidant vitamins

Recent evidence that oxidative damage of LDL and other lipoprotein fractions are associated with foam cell formation and atherogenesis have led to speculation about the benefits of antioxidant vitamins such as beta-carotene, vitamin C, vitamin E. Diets rich in fruits and vegetables containing high level of beta-carotene have been demonstrated to reduce risk of CVD. Vitamin E has been shown in two large epidemiologic studies to reduce CVD in those choosing to take Vitamin E supplements.

However, there may be some risk of hemorrhagic stroke with vitamin E. Definitive trials are currently being performed. At present, patients should be encouraged to eat 5-9 daily servings of fruits and vegetables, which are rich in carotenoids and other antioxidant vitamins.

Alcohol

Many studies have demonstrated the benefits of moderate alcohol consumption on CVD prevention. Men and women who drink on average 1 drink (1 oz) per day are 21% less likely to die from any cause and 30-40% less likely to develop CVD compared to non-drinkers.⁸ The health benefits of alcohol appear to be true for any kind of alcohol with no special benefits to red wine. Drinking more than 4 drinks per day is unhealthy — leading to increased risk of cirrhosis, alcoholism, breast cancer and motor vehicle accidents. Physician recommendations

... most low fat dietary regimens studied lowered total blood cholesterol by 12-15% with a 12-24% reduction in CHD events.



should be for those who drink alcohol to average no more than 1 drink per day. If patients do not drink, they should not be recommended to start drinking alcohol since the benefits in this group do not clearly outweigh the risks.

CLINICAL PARADOXES

Given the quality and consistency of the clinical trial evidence shown in Table 1, what remains perplexing is why clinicians don't uniformly see these results in their clinical practices. In a recent meta-analysis of 17 clinical trials comparing dietary interventions of a least 3 months duration in free living populations, Brunner et al found only modest reductions in CHD risk.⁹ Diets lowered fat only 2.5% as a percentage of food energy with a reduction in total cholesterol of 8.5 mg/dl. These apparent discrepancies with the above mentioned clinical trials may be related to dietary non-compliance, due to both lack of motivation by patients who did not perceive a risk or to the lack of intensity of the dietary intervention with little follow-up. An important explanation of these results may be the variability in response to diet by individuals compared to population norms. Figure 1 from Shaefer et al's data on volunteers in metabolic wards demonstrates a wide range of responses in plasma total and LDL cholesterol from an increase of 5% to 40% reduction.¹⁰ This wide range in response may well explain the clinical picture of diet responsive and diet resistant individuals seen in clinical practice.

Another important paradox that clinicians observe is that by placing a patient on a low fat diet (i.e., replacing saturated fat with carbohydrates or polyunsaturated fats), the clinicians notice a lowering HDL cholesterol and therefore worsening of total cholesterol/HDL ratio. The importance of HDL cholesterol in predicting CHD risk is demonstrated in Figure 2

Table 3. American Heart Association Dietary Guidelines

- Total fat intake should be no more than 30 percent of calories.
- Saturated fatty acid intake should be less than 10 percent of calories.
- Polyunsaturated fatty acid intake should be 8 to 10 percent of calories.
- Monounsaturated fatty acids make up the rest of the total fat intake, about 10 to 15 percent of total calories.
- Cholesterol intake should be less than 300 milligrams per day.
- Sodium intake should be no more than 2,400 milligrams (2.4 grams) per day.

For specifics on how to translate these recommendations into patient advice, see AHA's excellent website. (<http://www.americanheart.org/>)

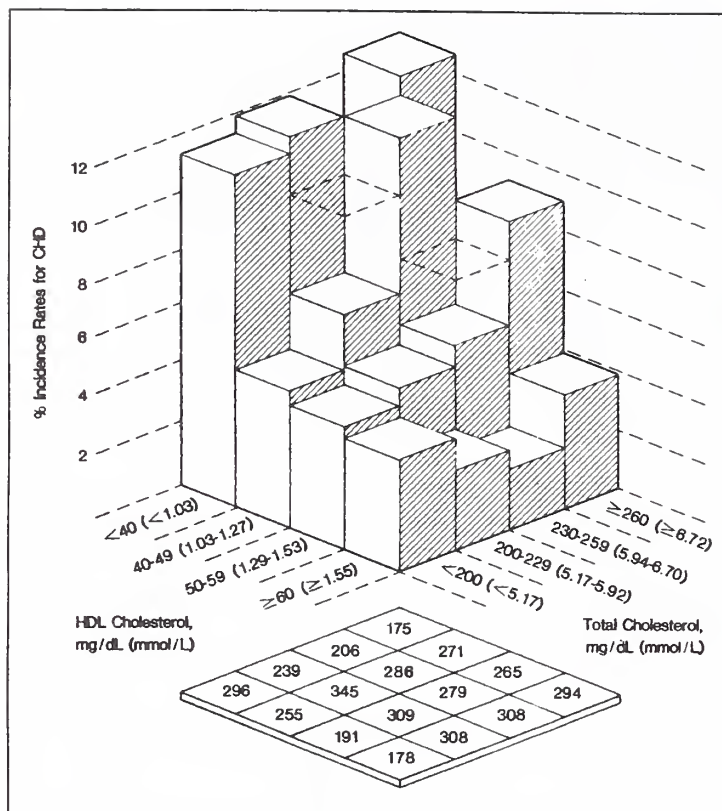


Figure 2. Incidence of coronary heart disease (CHD) in four years by high-density lipoprotein cholesterol (HDL-C) and total plasma cholesterol level for men and women free of cardiovascular disease. Dashed lines indicate two bars that are hidden from view: HDL-C less than 40 mg/dL (<1.03 mmol/dL), total cholesterol 230 to 259 mg/dL (5.95 to 6.70 mmol/L), rate=10.7%; HDL-C 40 to 49 mg/dL (1.03 to 1.27 mmol/L), total cholesterol greater than or equal to 260 mg/dL (6.72 mmol/L), rate=6.6%. Diagram at bottom shows number of observations from combined sample that fell into each cell and were therefore at risk for CHD.

from the Framingham Heart Study.

This simultaneous lowering of HDL and LDL cholesterol seems to be especially true for patients who don't lose weight or who don't start to exercise regularly. The clinical finding has confirmed recently in both metabolic ward and in clinical trials of free living individuals.^{11,12} It is therefore recommended that when reducing saturated fat in the diet, the calories should not be replaced and that weight loss and regular exercise should be recommended in most circumstances. In underweight individuals, saturated fat calories could be

replaced with monosaturated fats such as olive oil, avocados and nuts, which will increase HDL cholesterol while maintaining the LDL reduction in most circumstances.¹³

SUMMARY

To decrease risk for CVD, reduce and prevent risk factors such as elevated blood cholesterol and obesity, patients should follow the dietary recommendations from the American Heart Association (AHA) (Table 3) and the Dietary Guidelines for Americans (Table 4).

Many patients can be helped by educational materials and referral to a qualified nutritionist

(see Counseling article in this issue for more details on educational resources).

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Table 4. Dietary Guidelines for Americans

- Aim for a healthy weight.
- Be physically active each day.
- Let the Pyramid guide your food choices.
- Choose a variety of grains daily, especially whole grains.
- Choose a variety of fruits and vegetables daily.
- Keep food safe to eat.
- Choose a diet that is low in saturated fat and cholesterol and moderate in total fat.
- Choose beverages and foods to moderate your intake of sugars.
- Choose and prepare foods with less salt.
- If you drink alcoholic beverages, do so in moderation.

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It's Only Natural: Use of "Natural" Products From the Clinician's Perspective

Dorothy DeLessio, MS, RD, and Anne Hume, PharmD, BCPS

The use of alternative medicine in the United States increased 380% between 1990 and 1997 with usage becoming more common in specific patient groups. Individuals choose alternative medicine because of an interest in health promotion and disease prevention, the lack of treatment options for serious illnesses, dissatisfaction with conventional therapies, belief in the superiority of natural products, preference for personal involvement in decision-making process, and/or cultural or spiritual preference.¹ Fewer than 40% of individuals inform their physician of the use of alternative medicine. This finding has not changed during the past seven years.² Conversely, many health care providers, whether due to the dearth of sound scientific information on natural products or to a discomfort with a non-traditional medical model, have been uncomfortable with inquiring as to the use of this type of medical care. This situation has been described as "don't ask and don't tell".² The increased use of natural products raises important questions about potential safety and efficacy, as well as drug interactions, for primary care providers. The purpose of this article is to review issues related to natural products in an office-based practice.

NATURAL PRODUCTS

The term natural product is used broadly to include medicinals other than pharmaceutical drugs. It is used interchangeably with the terms: herbals, botanicals and nutritional supplements.

There are over 20,000 natural products available in the United States. The most commonly purchased herbal products in Rhode Island are: echinacea, ginkgo, glucosamine (and chondroitin), kava, St. John's wort, and saw palmetto. Special products are now

being targeted to specific patient groups. For example, a pediatric product containing St. John's wort, kava, valerian and melissa extract has been advertised to help children relax naturally. The claim is that the product "supports and soothes the nervous system." While the widespread use of these products has been recognized, information on their effectiveness, potential adverse effects and drug interactions remains sketchy at best. Herbals are pharmacologically active substances and cannot be discounted as nontoxic because they are "natural". The marketing and use of natural products for health maintenance or to self-treat benign conditions raises ethical questions around safety, efficacy, cost, and risk-benefit ratio. Self-treatment with natural products for more serious conditions is of greater concern because of the increased potential for interactions with prescription drugs as well as the replacement or delay of proven therapies. Table 1 lists some natural products and their common indications.

Herbals are pharmacologically active substances and cannot be discounted as nontoxic because they are "natural".



FORMS USED

Herbal products come in the following forms depending on the intended use:

- Bulk herbs are the raw plant mate-

Abbreviations Used:

DSHEA	Dietary Supplement and Health Education Act
FDA	Food and Drug Administration

rial, either fresh or dried, and are used to brew teas, infusions or decoctions. This form is generally the cheapest.

- Teas are the weakest of the herbal preparations. They are prepared by steeping fresh or dried herbs in boiled water for about 10 minutes.
- Infusions are stronger teas made by steeping for at least 20 minutes.
- Decoctions are stronger than infusions. They are made by boiling then simmering the plant material in water for 20-30 minutes and then strained.
- Tinctures are made by extracting bulk herbs with a mix of water and alcohol or glycerin and can be taken straight or added to beverages such as fruit juices.
- Capsules and tablets are popular because of their convenience. Most any form of the herb can be used to produce a highly concentrated extract.

REGULATION

From a regulatory perspective, natural products are dietary supplements and have the legal status of asparagus. Dietary supplements do not need to be proven safe or effective nor do they need to contain a minimum amount of active ingredients in order to be marketed. The Dietary Supplement and Health Education Act (DSHEA) of 1994 allows manufacturers of natural products to make claims regarding the ability of their products to alter (physical) structure or function. They cannot claim treatment, diagnosis, cure or prevention of disease. For

example, a label can state that the product "can enhance heart function", but not that it "is useful in the treatment or prevention of heart disease." It is common for consumers to misinterpret labels and believe claims associated with the product to be approved by the Food and Drug Administration (FDA). DSHEA states that herbal products can remain on the market if they do not make specific health claims and have not been proven to be unsafe. Herbal supplements do not require testing for safety or effectiveness in meeting their claims prior to being put on the market. As a result, the supplement industry has become increasingly aggressive in making certain health claims. Few products have been tested in well-designed randomized, double-blind clinical trials. Most of the research has been done in Europe with Germany leading the way with the establishment of Commission E. Commission E is the interdisciplinary commission of scientists and health professionals charged by the German government with reviewing herbal medicines.

While the natural products industry is moving to police itself, there are no universal standards for quality, pharmacological activity, or purity for herbal supplements in the United States. The FDA does not test products for contaminants or quantities of advertised active ingredients. Independent tests of herbal supplements have found wide variations in the quantity of active ingredients, with some supplements containing little or none. The presence of contaminants is of particular concern. Heavy metals, prescription drugs such as corticosteroids, digoxin, benzodiazepines and toxic compounds have been found in herbal preparations. This is a particular problem with products imported from Asia.³ The FDA has proposed new rules regarding the examination of health claims and labeling of dietary supplements to ensure accuracy and consistency. Although the proposed new rules do not change the DSHEA regulations, they will put additional requirements into place and may clarify allowable health claims.

DOSAGE AND STANDARDIZATION

Herbal products are available in a variety of dosages due to the lack of legal standards in these products' harvesting, processing, and packaging and in the paucity of clinical trials identifying the active ingredients in the herb. Some standardized products are available in the United States. A product is considered standardized when a guaranteed level of a certain constituent or group of constituents from the herb is present in the final product. This level is usually expressed as a percentage of the weight of the extract. Extracts of an herb are standardized to contain a certain percentage of its active ingredient, if it has been identified. If the active ingredient is not known, a major component or a class of components may be used instead. Standardized extracts are the primary form used in Europe.

A thorough medication history including an individual's use of prescription and non-prescription medications should now also include specific questions directed at the patient's use of natural products and nutritional supplements.



IN THE OFFICE SETTING

Natural products are ubiquitous and have the potential for causing adverse effects in the following ways:

- Toxicity of main constituents
- Contamination with drugs, heavy metals, pesticides or microorganisms
- Allergic reactions
- Mistaken plant identities
- Drug interactions

The potential for drug-herb interactions may prove to be the most chal-

lenging issue confronting the office-based physician. In determining why a young woman has become pregnant despite use of an effective oral contraceptive, would a physician consider if she has started using St. John's wort for depressive symptoms? A patient stabilized on warfarin has developed unexpected bleeding. Would his health care provider inquire if he has recently started ginkgo biloba? A 50 year-old male patient taking a tricyclic antidepressant for a diabetic neuropathy has developed a significant increase in his blood pressure. Would the physician consider whether he has started using yohimbine for erectile dysfunction? The answer to these questions would probably be no. Interactions between natural products and prescription or nonprescription drugs are not widely known. Many reports of herb-drug interactions are sketchy and lack laboratory analysis of the suspected products. As previously mentioned, natural products' labels do not always accurately list all their contents. Adverse effects or interactions associated with a specific herb may actually be due to a contaminant or added ingredient.

The key to preventing and identifying any drug-related problem has always been a complete database of all medications. A thorough medication history including an individual's use of prescription and non-prescription medications should now also include specific questions directed at the patient's use of natural products and nutritional supplements. Since many individuals do not consider natural products to be "drugs" they may not remember to include them on their medication lists. David Eisenberg suggested a step-by-step approach to discuss alternative medical treatments with patients proactively.²

- Use neutral nonjudgmental terms when asking specifically about the use of natural products, couched in simple questions. For example, "What else are you doing to take care of your health?" or "Many people are taking herbs or natural products for a variety of reasons. Are you taking any like this or are

you considering taking any?" Avoid terminology such as "Alternative," "complementary" or "unorthodox." These can be perceived as judgmental and inhibit discussion.

- For patients using natural products, record the dosage, duration of use, the intended reason for using each product, perceived benefit and any side effects experienced.
- If the patient cannot recall all natu-

ral products or dosages taken, request him/her to bring that information at the next appointment.

- Treat the patient as a partner in determining any problems associated with the use of herbal remedies.
- Once the use or intended use of herbal products has been established, evaluate the safety and appropriateness of their use by the patient.
- Caution should be taken when patients are using combinations of natural products and conventional medications that may produce similar effects. Many herbal products including garlic, ginger, ginseng, ginkgo and feverfew possess some antiplatelet properties and should be not be used with drugs such as warfarin or aspirin which are commonly prescribed in older persons for heart disease and stroke.
- In patient education - again, delivered with sensitivity to the patients' reasons for using herbals - discuss the following topics:
 - the lack of quality regulation and standardization of natural products
 - potential natural product related problems associated with the patient's medical condition and medications
 - the lack of information on interactions
 - the need to report any problems associated with the use of the product
 - the importance of continuing to take prescribed medications.
- Discourage the use of products with known toxicity.
- For uncommon natural products that the patient is taking, consult with pharmacists or drug information centers regarding standard use, dosage form, dose, dosing frequency, side effects, and potential impact on conventional treatments and all disease states. A list of information resources and a patient handout are provided at the end of this article.
- Review the patients' allergies with

Organizational Sources of professional and patient information on Dietary Supplements

- American Dietetic Association
National Center for Nutrition and Dietetics
phone: (900)-225-5267
www.eatright.org
- American Botanical Council
P.O. Box 1443454
Austin, TX 78714-4345
phone: (512) 926-4900 or (800) 373-7105
www.herbalgram.org
- American Herbal Pharmacopia
P.O. Box 5159
Santa Cruz, CA 95063
phone: (831) 461-6317
www.herbal@got.net
- The Dietary Supplement, a newsletter updated monthly
www.thedietarysupplement.com
- Food and Drug Administration
Department of Health and Human Services
Rockville, MD 20857
www.fda.gov/fdahomepage.html
- NAPALERT (National Products Alert Database Program for Collaborative Research/Pharmaceutical Sciences)
College of Pharmacy
University of Illinois
phone: (312) 996-2246
www.info.cas.org/onlinecatalog/napalert.html
- National Institutes of Health (NIH), Office of Dietary Supplements
phone: (301) 435-2920
www.dietary-supplements.info.nih.gov
- Consumer Lab, reporting on the quality of selected products
www.consumerlab.com
- A free commercial site with a section for health professionals on herbal products
www.tnp.org

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Table 1. A Sample of Natural Products Commonly Used in Rhode Island

NATURAL PRODUCT	COMMON USE	ADVERSE EFFECT/DRUG INTERACTION
Black cohosh (Cimicifuga racemosa)	Not proven Menopause symptoms PMS, dysmenorrhea	GI upset, headaches, CV depression, hypotension No proven drug interaction Contains tannins, may reduce iron absorption
Echinacea (Echinacea Angustifolia, Echinacea Palida)	Shown effective immune system stimulation, treating the common cold	No adverse effects or drug interactions reported May be immunosuppressive with prolonged use (more than 6-8 weeks); not recommended for patients with autoimmune disease
Feverfew (Tanacetum parthenium)	Shown effective in Prophylaxis and treating of migraine.	Possible GI effects, may stimulate menstruation, contraindicated in pregnancy and lactation, Contains tannins—may reduce iron absorption Caution with anticoagulants—may increase bleeding Caution with antiplatelet medications—may reduce platelet aggregation No documented problems
Ginkgo (Ginkgo biloba)	Shown to increase peripheral blood flow; used in treatment of intermittent claudication, hyperviscosity cerebral vascular insufficiency, dementia, tinnitus, vertigo	Large doses needed to be effective, may cause GI upset, inhibits platelet aggregation—caution with anticoagulants and aspirin. Caution with chronic use.
Garlic (Allium satvum)	Large doses shown effective in slightly reducing cholesterol. LDL, TG and increasing HDL; may have antibacterial, antifungal and antithrombotic effect; not proven effective in treating hyperglycemia	Shown to inhibit platelet aggregation. May interact with anticoagulants. Rarely causes allergic reaction. Heat and acid destroy active ingredients.
Glucosamine (glucosamin sulfate)	The combination of Glucosamine and chondroitin has been shown to have some modest benefit in the treatment of degenerative joint disease.	May reduce effectiveness of diuretics. May be associated with increased blood glucose levels in diabetics.
Ginseng (Panax ginseng-Korean ginseng; Panax quinquefolium- American ginseng) NOTE: Siberian ginseng is a different species	Not proven Used as an adaptogen, not effective as an aphrodisiac	Contents of commercial products vary widely and are often adulterated Headache, insomnia, palpitations, nervousness, excitation, estrogenic effects, Caution with hypertensives, decreased effectiveness of diuretics (furosemide), may decrease efficacy of warfarin.
Kava (Piper methylisticum)	CNS depressant effects Shown effective in treatment of insomnia and anxiety	Prolonged use causes eye disturbances, skin yellowing, dryness and scaling-reversed with discontinued use, Potentiates alcohol and other CNS depressants, note may increase sedation caused by antihistamines Contraindicated in pregnancy, lactation, depression Discontinued use two weeks prior to surgery due to possible interaction with anesthesia
St. John's Wort (Hypericum perforatum)	Shown to be effective in treating mild to moderate depression, sleep disorders and anxiety	May cause photodermatitis Do not use with drugs that increase photosensitivity. Reduces concentrations of digoxin, OCP, indinavir, and cyclosporin. More drug interactions likely to be identified in the future. Has not been shown to have MAO inhibitor activity. Discontinue drug 2-3 weeks prior to surgery may alter heart rate or BP. Potential to causes serotonin syndrome if taken with SSRIs.
Saw Palmetto (Serenoa repens)	Shown effective in treatment of benign prostatic hyperplasia (BPH) Possible anti-inflammatory NOT proven useful to prevent male baldness	No known drug interactions May cause stomach upset Effect on other hormone therapy unknown May inhibit iron absorption
Soybeans (Glycine max)	Proven useful in reducing heart disease risk. May be useful, but not proven, in treating menopausal symptoms, prevention of osteoporosis, breast cancer and diabetic nephropathy	Rare allergic reaction Possible GI upset Reduces absorption of levothyroxine-should be taken 2-3 hours prior to soy consumption

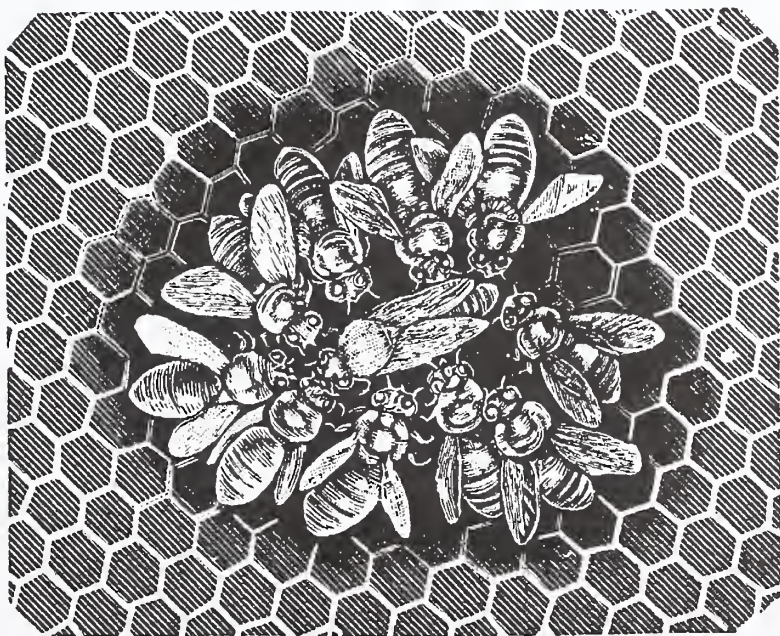
FOR PATIENTS: NATURAL PRODUCTS, HERBS AND NUTRITIONAL SUPPLEMENTS

Important suggestions for people who take or plan to take natural products, herbs or other nutritional supplements:

- * Tell your doctor, pharmacist, and other health care providers ALL products you are taking: prescription medicines, vitamins, minerals, herbs, other nutritional supplements and all over-the-counter medications. There may be important interactions that you need to know about.
- * Contact your doctor or pharmacist if you have ANY side effect (or reaction) linked to a product even something like changes in the color of your urine. Stop taking the suspected herb or supplement until you can reach your doctor or pharmacist.
- * Some natural products, herbs or other nutritional supplements may cause dangerous complications during surgery such as increased bleeding, irregular heart rhythm, and extended operating time of anesthesia. Talk with your doctor about the best time to stop taking the herb or other product prior to surgery.
- * Use only high-quality, certified or standardized products. Avoid foreign sources unless advised otherwise by your doctor. Some foreign products contain toxic contaminants.
- * Take only one new product at a time, so that you can determine your body's response.
- * Get to know as much as you can about any herb, supplement, or medicine you are planning to take. Read as much as possible and ask questions.
- * Most medical experts recommend that you begin with a very mild dose of supplement or herb, generally 1/2 (or less) of the recommended dose.
- * If you are diabetic, check the effect of your herbal product on your blood glucose level.
- * Bring information on the products you are taking (such as the products, packages, or labels) with you to doctor appointments.

special attention to plant and pollen allergies.

- Schedule follow-up visits to assess and counsel around the effects of the use of herbal products. Herbs are weak drugs. While commonly-used natural products such as echinacea are generally safe, other herbal remedies may possess serious adverse effects (Table 1). The issue that



is particularly problematic to counsel patients about is the possibility of toxicity with chronic use.

- Document all information in the patient's medical record and share it with all members of the health care team.
- Report cases of apparent drug and herb interactions or suspected herb side effects to: FDA MED WATCH at: 1-800-FDA-1088 or at <http://www.fda.gov>.

Physicians cannot ignore the significance of natural products in everyday practice. Physicians are encouraged to educate themselves and their patients as to the safety and efficacy issues related to the use of natural products.

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The Role of Fiber in the Diets of Children

Christine M. Hardy MS, RD, LDN, and Randal Rockney, MD

Dietary fiber is indigestible material derived from edible plants. Fiber is classified according to its solubility in water: insoluble fiber does not absorb much water, while soluble fiber is capable of absorbing a substantial amount of water. Insoluble fiber includes cellulose, hemicellulose and lignin. These are found primarily in the skins or structural parts of fruits and vegetables and in whole grains or foods containing whole grains in which the germ or outer bran has not been removed during processing, such as brown rice and whole wheat bread. Sources of soluble fiber include pectin, gums and mucilages found mainly in fruit and vegetables. It is also present in some grains, especially oats and psyllium. Both types of dietary fiber have been identified as having important health benefits when consumed in adequate amounts.

RECOMMENDED INTAKE OF DIETARY FIBER FOR CHILDREN

The amount of fiber needed by children varies by the age and weight of the child. The American Academy of Pediatrics (AAP) recommends a dietary fiber intake of 0.5 gram/kilogram body weight, with a maximum intake of 35 grams/day. The Food and Drug food labels make recommendations for dietary fiber based on energy intake and do not differentiate between adults and children. The recommended fiber intake for a 2000 calorie diet is 25 grams/day and 30 grams/day for a 2500 calorie diet, or about 12 grams/1000 calories. These recommendations are lower than those of the AAP when applied to adolescent girls but considerably higher for young children when fiber intake is based on estimates of calorie requirements using the recommended dietary allowance for energy.

The food guide pyramid developed by the United States Department of Agriculture (USDA) does not make

specific recommendations for fiber intake, but an estimate can be made based on the number of servings and portion sizes of different types of foods recommended for consumption. Using this method, estimates of the recommended intake of dietary fiber are similar to those using the food labels: about 12 grams/1000 calories.

Finally, the American Health Foundation has proposed a different approach to estimating optimal dietary fiber intake for children using the age +5 method. This guideline estimates a range of recommendations from a minimum of 8 grams/day for a 3-year old to 25 grams/day for a 20-year old. Using this method, recommended fiber intake for young children is similar to that of the AAP (0.5 gram/kilogram) but lower for older children and adolescents. Table 1 summarizes the recommendations for optimal dietary fiber intake using the four methods.

TRENDS AND CURRENT INTAKES OF DIETARY FIBER AMONG U.S. CHILDREN

Results from a number of epidemiological studies support a role for dietary fiber in the promotion of optimal gastrointestinal function, as well as in lowering the incidence of several chronic diseases. Since eating habits and food choices are established in childhood, it is important to identify trends in fiber intake in this age group.

Over the past twenty years data on the dietary fiber intake of U.S. children have been obtained from several population-based surveys. (Table 2) Data analysis revealed a decline in dietary fiber intake despite a concomitant reduction in the consumption of total and saturated fat. Dietary fiber from ready-to-eat cereals, other grain products and combination foods increased while the consumption of fiber from fruits and vegetables decreased.

Abbreviations Used:

AAP	American Academy of Pediatrics
USDA	United States Department of Agriculture

DIETARY FIBER IN THE PREVENTION AND TREATMENT OF CONSTIPATION

Constipation and the accompanying abdominal pain are frequent complaints among children. This is not surprising since the average dietary fiber intake for children ranges from 76-100% of recommended using the age + 5 method. Fiber intake tends to be adequate in early childhood but drops significantly in adolescence. Adequate fiber and water intake is essential for the passage of soft stools on a regular basis.

Although both types of fiber contribute to optimal gastrointestinal function, insoluble fiber plays a more significant role. The presence of insoluble fiber in the small bowel reduces transit time, and increases stool weight and frequency. Soluble fiber absorbs water in the small intestine, increasing stool size. It also provides fermentable substrate to colonic bacteria. Fermentation of soluble fiber by these bacteria results in the production of short chain fatty acids, which are utilized as a fuel source by the colonocytes. This is also a source of flatulence. The effects of either type of fiber are influenced by the dietary source of fiber as well as other factors that may be present in the luminal environment.

A number of studies in adults also suggest a potential role for dietary fiber in preventing cancer of the colon, breast, ovaries and prostate. Development of healthy eating habits in childhood, including increased consumption of high fiber foods may have both short and long-term beneficial effects.

EVIDENCE FOR A ROLE OF DIETARY FIBER IN TREATING HYPERCHOLESTEROLEMIA

There is growing evidence to support a role for soluble fiber in lowering the low-density lipoprotein fraction of serum cholesterol. (See Cardiovascular Disease and Nutrition," by Charles B. Eaton and Kim M. Gans). The specific mechanisms of this lipid-lowering effect have yet to be identified, but it is likely that there are several. One proposed mechanism is related to the absorption of luminal fat by soluble fiber resulting in a net reduction in intestinal absorption. A second possibility, which has been borne out by numerous studies, is the increased excretion of bile acids induced by certain soluble fibers. This increase in bile acid excretion results in an increased demand for bile acid synthesis with an increased conversion rate of cholesterol to bile acids. If this conversion rate exceeds the rate of cholesterol synthesis then serum cholesterol levels decrease. Another proposed mechanism involves the effects of the increased viscosity of luminal contents caused by the presence of certain types of soluble fibers. This more viscous environment may interfere with absorption of cholesterol or bile acids in the small intestine. This property appears to be related to specific types of fiber. It is also possible that fiber alters the bile acid profile by the differential binding to bile acids which may result in decreased absorption or synthesis of cholesterol. Certain types of soluble fiber may also have a direct effect on cholesterol synthesis by suppressing lipogenesis.

Most of the literature that has examined the lipid-lowering effects of fiber has been conducted in adults. Only a few studies have been performed with children. In most of those pediatric studies, the sample sizes were small ($n < 49$), but the observed effects of fiber were similar to those seen in adults.

THE ROLE OF DIETARY FIBER IN THE MODIFICATION OF THE GLYCEMIC RESPONSE

There is a decrease in the postprandial glucose curve when soluble fiber is included as part of a meal. The

primary contributor to this reduction appears to be the delay in gastric emptying that occurs as a result of the increased viscosity caused by the presence of soluble fiber. Starch digestion is also delayed, as is the rate of glucose absorption in the small intestine. These are important factors to consider when providing dietary guidance to individuals of all ages with diabetes.

Fiber intake tends to be adequate in early childhood but drops significantly in adolescence.



THE ROLE OF DIETARY FIBER IN THE PREVENTION AND TREATMENT OF OBESITY

The incidence of obesity during childhood is increasing at an alarming rate. Many factors including genetic, environmental, and socioeconomic play a role in the development of obesity. From the perspective of dietary intake, total caloric intake has not been associated with obesity, but total fat intake has been identified as a factor. An inverse correlation seems to exist between the rate of obesity and total dietary fiber intake in some developing countries. Conversely, the incidence of obesity in developed countries is high while fiber intake is relatively low. This relationship appears to be due to the effects of fiber on food intake, digestion and absorption of nutrients, and carbohydrate metabolism.

As mentioned previously, the presence of high fiber foods in the gastrointestinal tract appears to modulate carbohydrate metabolism through several mechanisms. These mechanisms also include blunting of the insulin response that may

affect satiety. A diet high in fiber will also reduce the digestibility of dietary carbohydrate and protein, decreasing metabolizable energy. The impact of fiber on small intestinal transit time, and subsequent increase in fecal energy losses further affects availability of nutrients, especially energy.

The effect of fiber on several aspects of food intake is probably the most important denominator in the relationship between dietary fiber and obesity. Foods high in fiber are usually low in fat and total calories. These foods tend to require more chewing and a longer time to eat, which results in earlier satiety. The effects of fiber on gastric emptying rate may further decrease hunger and extend satiety.

Few studies have examined the role of dietary fiber in the prevention or treatment of obesity in children. The limited data, however, suggest that heavier children consume less dietary fiber, and an adequate fiber intake appears to be a negative predictor of obesity in children. The main benefits of fiber seem to be related to its lower caloric density and its effects in maintaining satiety.

POTENTIAL RISKS OF A HIGH FIBER DIET IN CHILDREN

Ironically, the same effects of fiber that are perceived as beneficial in the prevention and treatment of obesity also may be considered harmful in certain populations of children. Foods that are high in fiber tend to be bulky, have reduced energy density, and require more chewing than low fiber foods. This combination of factors can cause early satiety and decreased energy intake; raising the risk that there may be insufficient energy consumed for growth. This is

Table 1. Recommendations for fiber intake during childhood

Organization	Recommended Daily Intake
American Academy of Pediatrics	0.5 gm/kilogram
Food & Drug Administration	12 gm/1000 calories
U.S. Department of Agriculture	12 gm/1000 calories
American Health Foundation	Age + 5 (grams)

Web sites for more information:

The American Dietetic Association:
<http://www.eatright.org>

USDA Center for Nutrition Policy and Promotion:
<http://www.usda.gov/cnpp/>
<http://www.usda.gov/cnpp/kidspyra/>

The American Academy of Pediatrics:
<http://www.aap.org>

of particular concern in the child younger than five years of age. The increased intestinal transit role associated with foods containing insoluble fiber reduces the time nutrients are exposed to the intestinal brush border, decreasing nutrient digestion and absorption. This results in increased fecal energy losses. Few studies have examined this effect of fiber in children, but it appears that the magnitude of this effect is relatively small and

is probably insignificant in children with a nutritionally adequate diet.

Certain fibers also interfere with bioavailability of some minerals. The presence of phytates derived from some high fiber foods form insoluble compounds with minerals, especially calcium and zinc. Other foods contain oxalic acid,

which interferes with iron and calcium absorption. There is, however, a compensatory increase in intestinal absorption of minerals if the amount of fiber in the diet is increased slowly. The majority of children in the United States do not appear to be at risk of compromising growth or mineral nutrition by consuming a diet high in fiber. Children less than five years of age, adolescents who eat a mineral-poor diet,

children of low income households who may have a nutritionally inadequate diet, and children consuming a vegan diet of poor quality or quantity are considered to be at higher risk of developing deficiencies related to consuming a high fiber diet.

PRACTICAL CONSIDERATIONS

Using the age +5 guideline simplifies estimating fiber requirements for children. It is a useful tool for health care providers to educate the caregivers of children, including parents, teachers and other child-care providers, as well as the children themselves. Increasing the fiber content of a child's diet should be done gradually. This will avoid the gastrointestinal discomfort (cramping, bloating, gas, diarrhea) which can result from a sudden increase in dietary fiber. Adequate water intake is also essential to improve intestinal transit and aid in increasing stool mass.

It is now quite easy to estimate dietary fiber requirements for children; however, it may not be as simple for many children to have access to foods that are the best sources of this fiber. Fruits, vegetables and foods containing whole grains are often more expensive than their low-fiber substitutes and are less accessible to families living on a limited income. This will affect the nutritional adequacy of their diets. It is important to take a family's financial resources into consideration when making recommendations to increase fiber intake.

Table 2. Trends in dietary fiber intake during childhood

Age (Yr)	1977-1978 NFCS* mean	1987-1988 NFCS intake (gm/day)	1994-1996 NHANES#
2-5	8.9	8.2	9.6
6-11	12.1	11.5	13.1
12-18 males	15.2	14.0	17.4
12-18 females	11.0	10.6	13.0

*National Food Consumption Survey

#National Health and Nutrition Examination Survey

Table 3. Fiber containing foods for Children

Food	Amount	Grams of Fiber
Grains		
Raisin bran cereal	1 cup	7
Whole wheat biscuit cereal	1 cup	6
Oatmeal	1 cup cooked	4
Whole wheat bread	1 slice	2
Bran muffin	1 small	2
Fruit filled cereal bar	1	1
Vegetables		
Baked beans	1/2 cup	10
Cooked green peas	1/2 cup	4
Cooked broccoli	1/2 cup	2
Cooked carrots	1/2 cup	2
Baked potato	1/2 medium	2
Fruits		
Apple with peel	1 medium	3
Orange	1 small	2
Strawberries	1/2 cup	2
Raisins	1/4 cup	2

MEETING THE GOAL FOR DIETARY FIBER

A diet that includes a variety of foods, including fruits, vegetables and whole grains, can provide enough fiber to meet recommendations for different age groups. Including five age-appropriate servings of fruits and vegetables plus four to five servings of whole grain bread, pasta or rice will easily provide enough fiber for all age groups. It is also possible to increase the fiber content of the diet by adding unprocessed wheat, oat or rice bran or wheat germ to prepared foods such as mashed potatoes or casseroles in the event that children find other high fiber foods less appealing. Table 3 lists some fiber-containing foods for children.

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Physician-Delivered Nutrition Counseling: Why and How?

Christopher Sciamanna, MD, Kim M. Gans, PhD, MPH, LDN, and Michael G. Goldstein, MD

Diet is one of the most common topics addressed by physicians in counseling their patients. Nearly one in four patients report receiving some diet counseling during their visit.¹ Nevertheless, many physicians are unclear about how to provide such counseling. In this review, we will discuss the importance of dietary counseling, and ways to do it during a brief office visit, applying this information to the context of a typical patient with high blood cholesterol.

NUTRITION COUNSELING - WHY DO IT?

• Importance of Counseling

Eight of the leading causes of death in the United States are nutritionally-related; e.g., heart disease, certain cancers, obesity, stroke, hypertension, and Type 2 diabetes mellitus.

• Effectiveness of Counseling

Physicians can help patients change behavior, including diet.^{2,3} Encouraging patients to make dietary changes can help prevent or treat health problems such as obesity, hypertension,

and high blood cholesterol, and dietary counseling has been shown to reduce medication costs.⁴

• Barriers to Counseling

Physicians cite several barriers to providing nutrition counseling in office settings, including insufficient time, training, counseling expertise, reimbursement and optimism about people's ability to change their diet.^{7,8}

• Patients' Perspective on Counseling

Patients consistently report preventive services as a high priority for their health care and want physicians to provide life-style recommendations including nutrition counseling. Patients, rather than being alienated by physician inquiry about life-style, expect and may even welcome it.⁵ Patients also cite physician's failure to give such information as reasons not to request preventive services. Diet counseling of patients can strengthen the patient-physician relationship, enhance the quality of care received, and enhance the patient's satisfaction with treatment.⁶

Abbreviations Used:

ADA	American Dietetic Association
CPCP	Center for Primary Care and Prevention
HEI	Healthy Eating Index

NUTRITION COUNSELING - HOW TO DO IT?

The following principles of "patient-focused" behavioral counseling can help doctor-patient communications more effectively address lifestyle changes including dietary change.⁹

1. Accept the patient as he is.
2. Acknowledge that the patient has some answers.
3. Build the patient's confidence.
4. Set realistic expectations for self and patient.
5. Share responsibility.

With the principles of patient-focused counseling in mind, here are the steps of Behavioral Counseling, organized into "The Five A's of Behavioral Counseling," adapted from the National Cancer Institute's Four A's (Ask,

Advise, Assist, Arrange) of smoking cessation counseling.^{10,11}

A major tenet of behavioral counseling is the Transtheoretical Model's stages of readiness to change, which presumes that individuals go through five stages (precontemplation, contemplation, preparation, action, maintenance) on their way to making permanent behavioral changes. Dietary advice should vary with the patient's readiness. For example, a patient in precontemplation, who does not plan to make any dietary changes soon, would not be ready to set dietary goals. Advice for such patients may include increasing their awareness of the effect of diet on blood cholesterol. In contrast, a patient in preparation would be ready to discuss dietary changes.

1. ADDRESS THE AGENDA

Express the desire to talk about the patient's eating habits. For example, "I'd like to talk with you about how you are eating, because it can affect your blood cholesterol and your

weight." Sometimes behavior modification discussions can seem like they come out of nowhere - this broaches the topic in a friendly way, making no assumptions as to the quality of a patient's diet.

2. ASSESS

a. Behavior level.

Before giving nutrition advice, you must know the patient's current eating pattern. It is difficult to assess a patient's diet with a question or two. One approach is to do a quick 24-hour recall by asking patients to recall everything they ate yesterday (or in a recent typical day). Be sure to ask about condiments added to foods, methods of food preparation and portion size. This will give you information on meal patterns and snacking, food choices and preparation, i.e. if they are eating high fat foods, adding fat in preparation, and/or eating large portion sizes. Then you can compare the patient's eating pattern to the food guide pyramid and dietary guideline recommendations (Figure 1). (See Eaton and

Gans, "Cardiovascular Disease and Nutrition," this issue.)

You (or the patient) can also enter on the Internet one day's dietary intake into the Interactive Healthy Eating Index (HEI), an online dietary assessment tool. The HEI automatically "scores" the overall quality of the eating pattern in terms of its compliance with the food pyramid as well as fat, saturated fat, cholesterol and sodium guidelines. Specific suggestions are also given on how to make dietary changes. You can access this tool at www.usda.gov/cnpp/

There are also several written and computerized self-assessment tools that patients can complete at home or in the waiting room. These provide "user friendly" information on which dietary changes may be needed. (Table 1) Physicians can adapt questions from these brief surveys to ask verbally.

b. Readiness to change.

- "Have you thought about changing your diet at all?"
- "How much do you want to change

Figure 1. Resources for professional and patient information about nutrition

Books and articles

- * Krauss RM, Deckelbaum RJ, Ernst N, et al. Dietary guidelines for healthy American adults. A statement for health professionals from the Nutrition Committee, American Heart Association. *Circulation* 1996;94:1795- 800.
- * *Step by Step: Eating to Lower Your Blood Cholesterol*. Report of the National Heart, Lung, and Blood Institute. Washington, DC. 1994.
- * *Counseling to promote a healthy diet. Guide to clinical preventive services. 2nd ed.* Baltimore (MD): Williams & Wilkins; 1996: 625-42.
- * Nutrition recommendations and principles for people with diabetes mellitus. *Diabetes Care* 1999 Jan;22(Suppl 1):S32-5.
- * Hark L, Deen DJr. Taking a nutrition history: a practical approach for family physicians. *Am Fam Physic* 1999;59: 1521-8, 1531-2.

Web Sites For Dietary Guidelines, Food Guide Pyramid and Interactive Healthy Eating Index.

- * USDA Center for Nutrition Policy Promotion (www.usda.gov/cnpp/)
- * USDA Food and Nutrition Information Center (www.nal.usda.gov/fnic/)
- * American Heart Association (www.amheart.org) and (www.deliciousdecisions.org)
- * American Diabetes Association (www.diabetes.org/)
- * American Dietetic Association (www.eatright.org/fgp.html)
- * American Medical Association (www.ama-assn.org/insight/gen_hlth/nutrinfo/part1.htm)
- * National Heart, Lung and Blood Institute (www.nhlbi.nih.gov/)
- * Dietary Approaches to Stop Hypertension (DASH) (dash.bwh.harvard.edu/)
- * Tufts University Nutrition Navigator (ratings and links to many nutrition sites) (navigator.tufts.edu/)
- * Centers for Disease Control (www.cdc.gov)
- * Brown University School of Medicine Nutrition Academic Award (includes links to many sites) (biomed.brown.edu/courses/nutrition)
- * American Cancer Society (www.cancer.org/index.html)

Table 1. Self-Assessment Patient Diet Tools

1. Rate Your Plate.

Researchers at the Brown University Center for Primary Care and Prevention (CPCP) at Memorial Hospital of RI have developed a brief eating pattern questionnaire, Rate Your Plate, that asks about food habits related to blood cholesterol lowering (e.g., intake of meat, milk, sweets, etc.).^{12,16} Users are scored on a 21-63 point scale; individual scores can identify areas in need of changing. This tool can be used for counseling and goal setting as well as assessment, and has accompanying patient education materials. A web-based version and versions for other health conditions are being developed. Contact the CPCP at (401) 729-2894 for more information.

2. American Dietetic Association (ADA).

(www.eatright.org/pr/pressnm98f.html).

This site provides a brief instrument that examines the frequency of eating practices, focusing on the Food Guide Pyramid. Diets are scored on a 0-24 point scale; an individual's score can identify areas in need of changing. This site is not interactive; users must score themselves.

3. American Medical Association

(www.amaassn.org/insight/yourhlth/pernutri/checkeat.html).

This site provides another brief instrument, much like the ADA one, with slight differences in eating practices but with the addition of interactivity. Users receive their scores (ranging from 5-14) instantly and then are prompted to examine the areas in need of improvement.

your diet right now, on a scale of 1-10?"

An open-ended question such as the first will often lead to an eye-opening discussion about the patient's attitudes toward behavior change, experience with past behavior change and plans for future change. A close-ended question like the second can also be useful and can be followed up later by asking "What would make you more ready to change your diet right now?"

c. History of change efforts

- "Have you ever tried to cut down on the amount of fat you eat?"
- "What was that like?"

In behavior change, repeated trial and error provides the learning necessary to change for good. If the patient ate lower fat snacks and desserts for 6 months, you should congratulate him/her (build confidence), ask how s/he did it and what led to his/her changing back to higher fat choices after 6 months. If the patient went back to eating fatty snacks and sweets because

of problems making lower fat choices at parties and restaurants, this is a great opportunity for problem-solving.

d. Knowledge of risks.

- "What do you know about the link between what you eat and your health?"
- "I see that your cholesterol is high. What do you know about how your eating habits can affect your cholesterol?"
- "It seems that your weight is a little high. What do you know about how your eating habits can effect your weight?"

Nutrition knowledge varies widely. Data from 1994 showed that 60% of people knew about the dietary fat-heart disease link, though less than 10% knew about the saturated fat-heart disease link.¹³ The recent emphasis on dietary fat restriction has covered up the important differences between types of fat; this is a chance to make those clear. In counseling, every opportunity to personalize the message to the patient.

e. Reasons for changing or maintaining behavior.

- "What are the positive (negative) things about the way you eat now?"
- "What are the positive (negative) things about making a change in your eating habits?"

Try to understand the patient's attitudes and motivations. Mrs. R may have had a brother diagnosed with heart disease or another incentive for changing her diet that you could not have imagined. Many people know that they have unhealthy eating habits, but are ambivalent about change. Allowing them to discuss both sides of the issue can help them to convince themselves to change, but it can also uncover barriers (e.g., someone who eats out a lot) or opportunities (e.g., has trouble affording cholesterol medications) that may not have been uncovered otherwise. Letting the patient discover these issues is much more powerful than preaching to them.

3. ADVISE

"As your doctor, I need you to know that reducing the saturated fat and calories you eat is important for your health because it will help you decrease your blood cholesterol and maintain a healthy weight."

Strong, clear and personalized advice is best. Personalizing the message plays to the strengths of the clinician who knows the patient well and his/her medical history. Given the frequency of the diseases related to diet, most patients in adult practice will have a specific reason for changing their diet.

4. ASSIST

a. Offer to correct misunderstandings and provide new information

- "Would you like to talk about food choices that would be better for your health?"

The above quote may seem too passive for many physicians, but it focuses the counseling on the patient instead of on the physician. Though the word "physician" means teacher, you must first know whether or not

you have a willing pupil. If the answer is “yes,” you may use it as a chance to explain the differences between saturated and unsaturated fats and how replacing high-fat snacks and sweets with lower fat substitutes or using vegetable oils like Canola or olive oil, liquid or tub margarines would be better choices than butter or stick margarine.

b. Express empathy

- “It is understandable that you might not want to take steps to change right now.”
- “Changing your diet can be difficult.”

Some people believe that empathy may give the patient an “easy way out” - that if you prepare them for the possibility of failure, they will fail. In a study by Safran et al., one of the most powerful predictors of patient compliance with medications was a feeling that “my doctor cares about me as a person.”¹⁴ Empathy for the difficulty of behavior change is a part of successful behavior counseling.

c. Address barriers to change.

- “What might make it difficult for you to eat less saturated fat?”
- “Can you think of ways to overcome your craving for sweets, or choose sweets that may be lower in fat?”

Problem-solving is a critical part of behavior change. First, identify barriers to making the dietary change - typically of two types: (1) attitudes that maintain the problem behavior (e.g., “I don’t like vegetables”) and (2) triggers - situations or feelings that lead to the problem behavior (e.g., “When I go out to dinner, I always eat too much”). After identifying the problems, discuss ways that the patient may overcome the barrier. You need not have all the answers - remember that the patient has many of them. In this capacity, the physician may serve as a “facilitator” rather than a “lecturer.” People who have more positive attitudes about dietary change or who feel more confident about dealing with their triggers are more likely to change their behavior.

d. Consider smaller steps toward the

ultimate goal.

- “It is difficult to make big changes in how you eat all at once. Can you think of any small changes you can make now?”

“...neither the patient nor physician should view the counseling session as particularly stressful.”



This is especially true for precontemplators - people who are not ready to change. For them, simply thinking about the reasons they have for changing would qualify as a step forward, as they are most likely still defending their habits. Encouraging more fruits and vegetables is often a good first step, as this is a positive change rather than a sacrifice. Increases in fruits and vegetables can lead to decreases in other higher fat foods such as sweets and meats. Be as specific as possible. “How do you think you could eat more fruits and vegetables?” For example, eating a larger portion of vegetables at dinner, adding a fruit at breakfast and for a snack, etc.

e. Make goal(s) clear.

- “Now I’d like us to set a goal for what you will do before you see me again. From what you’ve told me, you are going to eat more fruits and vegetables by adding fruit to your breakfast, eating fruit for a snack and eating a larger portion of vegetables at dinner. Does that sound like a reasonable goal?”

Again, be as specific as possible, so the next time you see the patient, you won’t have to go through a lengthy assessment a second time. You’ll be able to say: “When I last saw you, you agreed to work on adding a fruit to your breakfast, eating a fruit for a snack and eating a larger portion of vegetables at dinner. How did that go?”

In addition, when the goal is clear,

you can give targeted patient information, instead of a generic guide to healthy eating. The patient will be more likely to listen — believing that it is more specific to his/her situation.

You can also give out patient education materials and suggest additional resources such as the Rhode Island Department of Health’s Nutrition Hotline (1-800-624-2700), quality nutrition web sites (Figure 1), or refer to a dietitian.

f. Refer interested patients.

- “It seems that you’re eating too much saturated fat, which may be the reason why your cholesterol is high. First, I would like to help you try to improve your eating habits, before I consider giving you medications. If you need medications, they work much more effectively if you’re eating a heart healthy diet. A nutritionist can help you make changes in your eating habits. Do you think you would be interested in seeing a nutritionist?”

For patients with health problems that can be improved via a dietary change, consider referral to a dietitian. Since some patients will not follow through with referrals, asking about their interest in a nonjudgmental way allows you to save time and keep the patient feeling involved in the decision process.

5. ARRANGE FOLLOW-UP

a. Keep the door open for further dialogue

- “Is this something you’re willing to talk about again when you come back?”

Setting the stage for future discussions is critical to maintaining a therapeutic doctor-patient relationship. Repeated “doses” of behavioral counseling are often necessary over months or years, and on a variety of topics aside from nutrition. Thus, neither the patient nor physician should view the counseling session as particularly stressful. This approach also reminds patients that they are an active member of the care team, thereby encouraging initiative.

b. Schedule follow-up appointment or telephone call to further discussion.

- "Would you be willing to schedule another appointment to talk about how your dietary changes are going and recheck your cholesterol?"

Scheduling a return visit will help the patient to understand the importance of making dietary changes and, like a student held accountable for homework, will encourage the patient to follow through on the goals set above.

CONCLUSION

Providing dietary counseling to your patients takes time, but is worth the effort in helping your patient to achieve better health as well as improving the doctor-patient relationship. Even if you cannot do everything this article suggests, physician advice alone has been shown to be more effective than no intervention at all. Combined strategies including physician advice, patient education materials and/or referral to a dietitian are likely to be the most successful in promoting long lasting dietary change.

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CME Background Information

This CME activity is sponsored by Brown University School of Medicine.

TARGET AUDIENCE

This enduring material is designed for physicians licensed in Rhode Island.

CME OBJECTIVES

After completing this CME activity, the primary care physician will be able to meet the following objectives.

Nutrition Learning Objectives

1. Learners will be able to list popular High Fat, High Protein diets and the proposed mechanism given by the proponents of such diets.
2. Learners will be able to articulate the typical metabolic response to high fat, high protein diet, calorically restricted diet and be able to discuss why short term weight loss usually occurs.
3. Learners will be able to describe the potential long-term health consequences of a high fat, high protein diet.
4. Learners will be able to describe at least three scientific studies that demonstrate that diet is important in preventing cardiovascular disease.
5. Learners will be able to describe the mechanism by which fatty acids affect lipoprotein metabolism.
6. Learners will be able to discuss the importance of fiber, B vitamins and Folate, soy protein, phytoestrogens, antioxidant vitamins, and alcohol on lipoprotein levels in preventing cardiovascular disease.
7. Learners will be able to discuss the apparent clinical paradox between the small effects of dietary change on many patients and the published reports from clinical trial and metabolic ward studies.
8. Learners will be able to list resources that allow them to assess nutrient-herb and herb-drug interactions.
9. Learners will be able to evaluate the health claims of common herbals.
10. Learners will be able to list common herbals used in Rhode Island.
11. Learners will be able to list common sources of fiber available to children.
12. Learners will be able to describe the role of fiber in preventing constipation.
13. Learners will be able to describe common drug-fiber interactions in children.
14. Learners will recognize the importance and feasibility of conducting dietary counseling with their patients.
15. Learners will discuss two methods for assessing patient's diets during an office visit.
16. Learners will discuss five principles of patient-focused nutrition counseling.
17. Learners will list at least three nutrition resources.

NEEDS ASSESSMENT

The need for this educational activity was supported by a Nutrition Academic Award from the Heart, Lung and Blood Institute of the National Institutes of Health, expressly to improve the nutritional education of practicing health care professionals.

ACCREDITATION STATEMENT

Brown University School of Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

CREDIT DESIGNATION

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DATE OF ORIGINAL RELEASE

This issue was published in November 2000. This activity is eligible for CME credit through November 2001.

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ACKNOWLEDGEMENT

The material contained in this issue is a result of the editorial work by Charles Eaton, MD, guest editor. The opinions expressed herein are those of the authors and do not necessarily reflect the views of the sponsors, publisher or the planning committee.

TO OBTAIN CREDIT

To obtain credit, please submit answer grid and \$25 fee to Office of Continuing Medical Education, Brown University. Respondents must receive a score of 70 or higher for credit.

Nutrition CME Questions

1. Weight loss occurs on HFHP diets largely because:
 - a. Dietary fat and protein promote early satiety, leading to decreased caloric consumption.
 - b. The elimination of carbohydrate content from the diet leads to depletion of glycogen stores, which results in obligate water loss.
 - c. Decreased insulin secretion, as a result of decreased carbohydrate consumption, inhibits lipoprotein lipase activity at adipose cells, making it difficult for lipids to be stored.
 - d. None of the above
2. HFHP diets have which of the following effects on lipid profiles?
 - a. Total cholesterol, HDL, LDL and triglycerides all typically improve initially after starting a HFHP diet.
 - b. The amount of weight loss is not related to changes in the lipid profile.
 - c. Improvement in blood lipid levels correlates with a decreased risk for CHD.
 - d. None of the above
3. HFHP diets may contribute to:
 - a. Increased risk for colon, breast and prostate cancer
 - b. Osteoporosis
 - c. Increased risk of CHD
 - d. All of the above
4. Which statement best describes the effects of fatty acids on lipoprotein physiology?
 - a. Saturated fat acids and trans fatty acids have the same effect on LDL receptor activity but the opposite effect on HDL cholesterol levels.
 - b. Monounsaturated fats have no effect on LDL clearance but increase HDL cholesterol.
 - c. Polyunsaturated fats (n-3) or omega-3 fatty acids increase LDL receptor activity and increase HDL cholesterol
 - d. Polyunsaturated fats (n-6) increase LDL receptor activity and therefore lower LDL cholesterol and decrease oxidation.
5. Which of the following is true regarding B vitamins?
 - a. A diet rich in fortified cereals, vegetables and legumes provides an excellent source of B vitamins and folate.
 - b. Well-designed clinical trials have shown that patients supplemented with B vitamins and folic acid are less likely to have recurrent coronary heart disease than those not supplemented.
 - c. Patients with renal insufficiency do not need B-vitamin supplements.
 - d. B vitamins such as B12, folate and pyridoxine play an important role in the metabolism of cholesterol and therefore coronary heart disease risk.
6. Which of the following is true regarding soy protein?
 - a. Diets rich in soy protein appear to lower total cholesterol, LDL cholesterol and triglycerides but have minimal effect on HDL cholesterol.
 - b. Soy protein is potentially harmful because of its antiestrogenic properties.
 - c. Sources rich in soy include fruits, vegetables and rice.
 - d. Large quantities (pharmacologic doses) of soy are needed to have any significant biologic effect, therefore diets rich in soy have little practical value.
7. Which of the following is true regarding CHD risk in clinical practice?
 - a. After lowering their saturated fat intake, most patients will experience reductions in total cholesterol and CHD risk.
 - b. Replacing saturated fat with carbohydrate or polyunsaturated fats usually results in raising of HDL cholesterol.
 - c. HDL cholesterol is not particularly useful in predicting CHD risk.
 - d. Individual responses to diet do not vary significantly from population norms.
8. Patients are likely to use alternative medicine for the following reasons:
 - a. dissatisfaction with conventional therapies
 - b. cultural preference
 - c. belief in the superiority of natural products
 - d. all of the above
9. In terms of regulation of herbal products, which of the following statements is true?
 - a. There are multiple well-designed clinical trials underway to study drug efficacy.
 - b. Most products are standardized, meaning a guaranteed level of constituents is present
 - c. A manufacturer can claim that a product enhances the immune system only after clinical studies have been conducted.
 - d. There are currently no standards in place regarding the purity or efficacy of herbal supplements in the U.S.
10. Which of the following characteristics do ginkgo, garlic and feverfew have in common?
 - a. active constituents are destroyed by heat and acid
 - b. effective in migraine prevention
 - c. interaction with anticoagulants
 - d. can be used to treat hyperglycemia
11. Which of the following statements about fiber is true?
 - a. Fiber is plant material that cannot be digested.
 - b. In terms of physiologic efficacy, there is no difference between soluble and insoluble fiber.
 - c. Soluble fiber is found predominately in whole grains.
 - d. Most children need at least 35g of fiber a day.
12. Which of the following is true about the relationship between fiber and constipation?
 - a. Soluble fiber plays a more significant role in preventing constipation than insoluble fiber.
 - b. Insoluble fiber in the small intestine increases stool weight and frequency.
 - c. Insoluble fiber provides fermentable substrate for colonic bacteria.
 - d. Soluble fiber in the small intestine increases stool weight and frequency.
13. True statements regarding high fiber diets in children include:
 - a. Insoluble fiber reduces nutrient digestion and absorption by increasing intestinal transit time.
 - b. Children under 5 years old need to worry less about consuming high fiber diets than older children.
 - c. High fiber foods tend to be bulky and thus have increased energy density.
 - d. None of the above
14. Recommendations for dietary fiber in children include all of the following except:
 - a. Adequate water intake is as important as fiber intake.
 - b. Including more fruits and vegetables in the diet is more important than trying to incorporate more whole grain breads, pasta or rice.
 - c. Increasing the fiber content of a diet should be done gradually.
 - d. Fiber recommendation for children is 5 plus their age, in grams.
15. Which of the following statements is true regarding nutrition counseling?
 - a. Physicians should offer the same advice regardless of the patient's readiness to change.
 - b. The 24-hour recall is the most accurate way to assess a patient's eating behaviors.
 - c. Setting small, clear, achievable goals is more effective than large-scale lifestyle changes.
 - d. Follow-up is not as important as initiating discussion.
16. Which of the following is important in counseling patients to make dietary changes?
 - a. Set realistic goals.
 - b. Express empathy for the difficulty of lifestyle changes.
 - c. Build the patient's self-confidence.
 - d. All of the above
17. Before giving nutrition advice, a doctor should:
 - a. Assess patient's current eating habits.
 - b. Determine the patient's willingness to make changes.
 - c. Determine the patient's knowledge of nutrition and its effect on health.
 - d. All of the above
18. When initiating a discussion about dietary changes with a patient, which of the following is the best example of the first thing to say?
 - a. "I'd like you to consider making some changes to your diet."
 - b. "Would you like to talk about food choices that would be better for your health?"
 - c. "I'd like to talk with you about how you are eating, because it can affect your blood cholesterol and your weight".
 - d. "Have you thought about making any dietary changes?"

Nutrition CME Registration Form

Circle one response for each question.

Print or type

1. A B C D
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18. A B C D

Name _____

Address _____

City, State, Zip _____

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DEADLINE FOR SUBMISSION

For credit to be received, please mail your registration with \$25 fee to Office of Continuing Medical Education, Brown University School of Medicine, Box G-A2, Providence, RI 02912. Submit your answers no later than November 30, 2001.

KEEP A COPY FOR YOUR FILES.

Retain a copy of your answers and compare them with the correct answers, which will be made available upon request, and receipt of submission requirements.

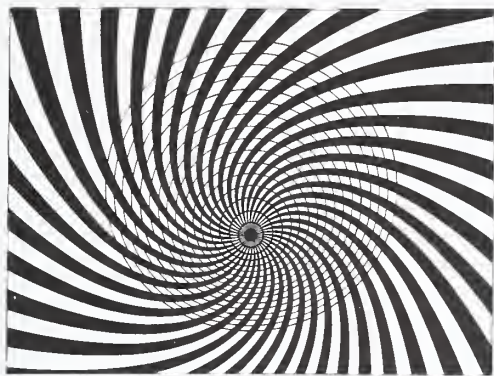
EVALUATION

Please evaluate the effectiveness of the CME activity on a scale of 1 to 5 (1 being poor; 5 being excellent) by circling your choice.

- | | | | | | |
|---|---|---|---|---|---|
| 1. Overall quality of this CME activity | 1 | 2 | 3 | 4 | 5 |
| 2. Content | 1 | 2 | 3 | 4 | 5 |
| 3. Format | 1 | 2 | 3 | 4 | 5 |
| 4. Faculty | 1 | 2 | 3 | 4 | 5 |
| 5. Achievement of educational objectives | | | | | |
| * Learners will be able to list popular High Fat, High Protein diets and the proposed mechanism given by the proponents of such diets. | 1 | 2 | 3 | 4 | 5 |
| * Learners will be able to articulate the typical metabolic response to high fat, high protein diet, calorically restricted diet and be able to discuss why short term weight loss usually occurs. | 1 | 2 | 3 | 4 | 5 |
| * Learners will be able to describe the potential long-term health consequences of a high fat, high protein diet. | 1 | 2 | 3 | 4 | 5 |
| * Learners will be able describe at least three scientific studies that demonstrate that diet is important in preventing cardiovascular disease. | 1 | 2 | 3 | 4 | 5 |
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| * Learners will be able to describe the role of fiber in preventing constipation. | 1 | 2 | 3 | 4 | 5 |
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| * Learners will discuss two methods for assessing patient's diets during an office visit. | 1 | 2 | 3 | 4 | 5 |
| * Learners will discuss five principles of patient-focused nutrition counseling. | 1 | 2 | 3 | 4 | 5 |
| * Learners will list at least three nutrition resources. | 1 | 2 | 3 | 4 | 5 |

Please comment on the impact that this CME activity might have on your practice of medicine.

Additional comments and/or suggested topics for future CME activities.



IMAGES IN MEDICINE

∞ Typhlitis ∞

Dirk Entzian, MD, and William W. Mayo-Smith, MD

An 18 year-old man with a history of leukemia had just completed a course of chemotherapy and presented with severe right lower quadrant abdominal pain. He was afebrile, but severely neutropenic with a WBC less than 0.1. Because of his severe abdominal pain, a computed tomography (CT) scan of the abdomen and pelvis was ordered.

Abdominal CT with oral and intravenous contrast (Figures 1 and 2) demonstrated a thickened cecum with stranding of the adjacent fat. There was no evidence of pneumatosis, focal fluid collection or abscess. The diagnosis of typhlitis was established.

The word typhlitis means inflammation of the cecum (*typhlon* means cecum in Greek). Typhlitis was first described in patients with leukemia who were neutropenic from chemotherapy. The reason for this location is not well known but may be due to ischemia. Patients without perforation or abscesses are usually treated with supportive therapy including hydration and intravenous antibiotics. CT is useful to establish the diagnosis of typhlitis and to differentiate it from other causes of right lower quadrant pain such as appendicitis or ureteral calculi.

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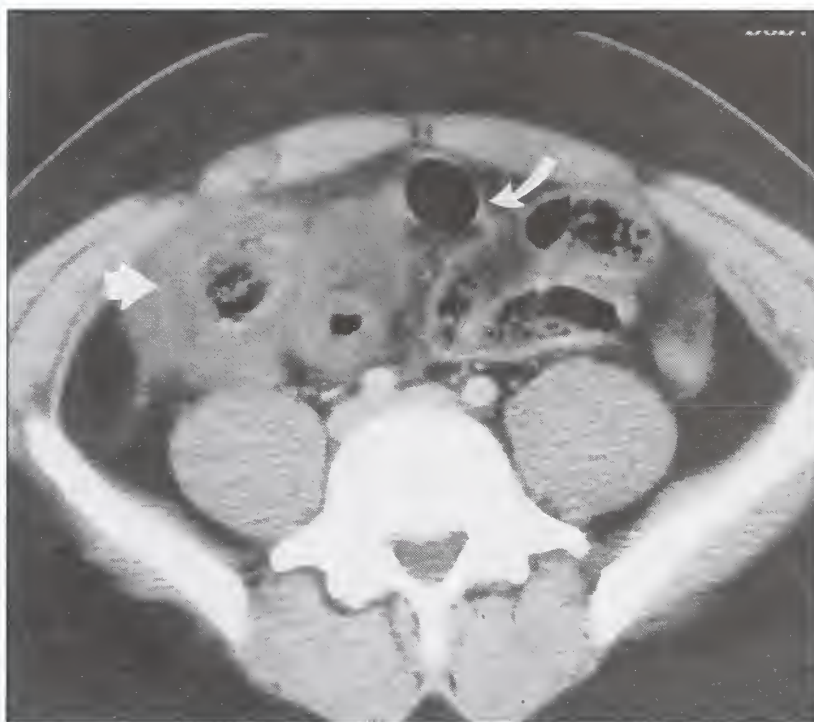
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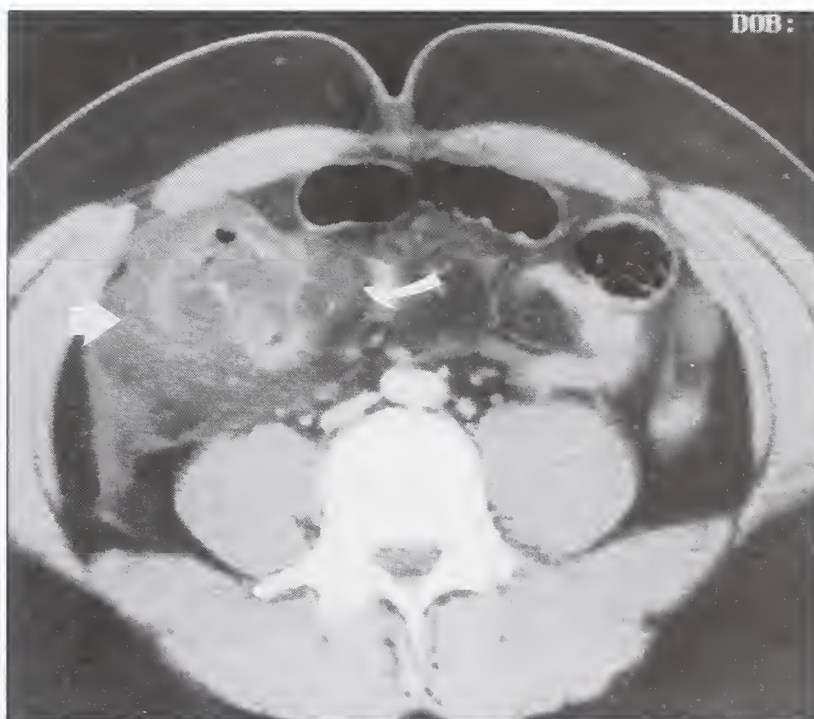
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Abbreviations Used:

CT computed tomography



CT of the lower abdomen with oral and intravenous contrast demonstrates a circumferentially thickened cecal wall (straight arrow). For comparison, normal colonic wall thickness in an uninvolved segment is demonstrated by the curved arrow.



Axial contrast-enhanced CT of the lower abdomen demonstrating a circumferentially thickened cecum (straight arrow) with stranding of pericolic fat (curved arrow).



Medicare's First Snapshot on Quality: What Does It Mean?

Raymond Maxim, MD

On October 4th, *The Journal of the American Medical Association (JAMA)*¹ published a first of its kind article describing the state of quality of healthcare delivered to Medicare beneficiaries. Stephen Jencks, MD, MPH, and much of the leadership of the Health Care Financing Administration (HCFA) authored the article. This data set is the result of an enormous effort to establish a baseline for future measurements and create a monitoring process for the quality of care delivered to Medicare beneficiaries. For the first time we are able to compare on a state-to-state basis 24 quality indicators. Each of these indicators represents a process-of-care acknowledged by professional consensus and strong scientific evidence to effect outcomes.

The indicators represent six different medical conditions (acute myocardial infarction, stroke, pneumonia, diabetes mellitus, heart failure and breast cancer). The data used for the hospital-based indicators were obtained by randomized chart review. The theoretical goal for these measures is 100% as those patients with possible contraindications were excluded from the sample. Obtaining data for the community-based indicators was more complex as chart review is not feasible for this large of a sample. The immunization data were obtained from the Behavioral Risk Factor Surveillance System (1997). The mammography and diabetes indicators were obtained from Medicare claims data.

As a region New England did well when compared to the rest of the nation. Five of the New England states rank in the top 10 states in the country. Rhode Island was the one New England state conspicuously absent from the top 10. The overall average rank for Rhode Is-

land was 24th. Does this mean the Rhode Island medical community does not provide good care? No, we believe that the care is good, but it suggests that we have areas where there are significant opportunities for improvement.

In a recent column in this journal we presented the data on the inpatient conditions.² In that article we identified areas that needed attention. Fortunately, each of the inpatient indicators relates to areas in which the hospitals and RIQP are already working closely together to make improvements. There is one of the indicators that I would like to highlight in this article: anticoagulation for those patients with atrial fibrillation. This suggests that as a nation we need to address this issue more closely. In Rhode Island, patients with atrial fibrillation are treated with warfarin only 59% of the time (these are patients who have an indication and no contraindication to the therapy). This ranks us at 12th in the country, which translates to a good opportunity for improvement.

In ambulatory care, the diabetes indicators, with exception of biennial eye exams in diabetics (rank 6th), place us in the middle of the country in performance. However, to put this higher ranking in eye exams in perspective our diabetic patients are getting biennial eye exams only 77% of the time despite the current recommendation for at least an annual exam. We are still lagging behind much of the country in obtaining HgbA1c measurements and lipid profiles in our diabetic patients. We are measuring biennial lipid profiles 54% of the time (rank 35th) and yearly HgbA1c only 70.6% of the time (rank 26th). The medical literature supports more frequent monitoring of both these indicators to reduce our patients' risk for the debilitating

Abbreviations Used:

HCFA	Health Care Financing Administration
JAMA	Journal of the American Medical Association

complications of diabetes.

Although, we have made significant progress in adult immunizations, our overall rankings are only 20th in influenza (67.7%) and 35th for pneumococcal (43%) vaccination rates. The range between states is small for both of these indicators. It would only take a few percentage points to put us at the top. But the ultimate goal is not to improve our rank; it is to prevent unnecessary hospitalizations or death in our patients from vaccine-preventable disease. Two new indicators, screening for both pneumococcal (rank 44th) and influenza (rank 46th) vaccination status in hospitalized patients are presented in this article. Until recently, little work has been accomplished in Rhode Island in this area. All of Rhode Island's acute care hospitals have been working with RIQP to implement inpatient-screening programs. They need your support. We need to be doing a better job of immunizing our patients no matter where they interact with the health care system. Each time a patient interacts with the system and does not receive an immunization for which they are eligible is a missed opportunity to prevent morbidity or mortality.

Like the rest of the outpatient indicators, our mammography ranking places us squarely in the middle of the country (rank 17th), with only 58% of our female beneficiaries receiving mammograms in a two-year period. This

**Table 1. National Clinical Topics
Baseline Results and Rankings - FFS Medicare Beneficiaries***

Area/Indicator	RI Rate	National Rank	Range of Rates in All States/Territories
AMI			
Aspirin at Admission	81.7%	36	65.3% - 96.6%
Aspirin at Discharge	86.9%	17	59.8% - 96.0%
Beta Blockers at Admission	75.7%	5	32.5% - 80.3%
Beta Blockers at Discharge	79.2%	11	46.7% - 92.7%
ACE Inhibitor at Discharge	83.3%	3	56.8% - 90.0%
Smoking Cessation Counseling	25.9%	48	19.4% - 70.2%
Reperfusion (PTCA/3 or Thrombolitics)	47 minutes	7	33.0 min. - 75.0 min.
Heart Failure			
ACE Inhibitor at Discharge	87.0%	2	71.1% - 87.7%
Pneumonia - In-patient			
First Antibiotic w/in 8 hours	80.4%	44	38.4% - 92.8%
First Antibiotic consistent w/guidelines	83.6%	7	54.9% - 87.1%
Blood culture before Antibiotic given	80.9%	36	65.2% - 93.4%
In-pat. screened/get flu vaccine	9.5%	46	5.9% - 39.2%
In-pat. screened/get pneumonia vaccine	6.8%	44	3.5% - 26.1%
Immunization			
Statewide influenza vaccine rate	67.7%	20	41.5%-74.4%
Statewide pneumococcal vaccine rate	43.0%	35	32.2%-59.4%
Stroke			
Antithrombotic at discharge	87.7%	4	72.0% - 90.1%
No Sublingual Nifedipine	95.4%	25	86.2% - 100%
Atrial Fibrillation			
Warfarin at Discharge	59.4%	12	30.7% - 65.3%
Breast Cancer			
Mammography	58.0%	17	47.4%-65.6%
Diabetes			
Annual Hba1c	70.6%	26	38.7%-85.3%
Biennial Eye Exam	77.4%	6	42.9%-79.7%
Biennial Lipid Profile	54.6%	35	30.5% - 72.7%

MI-RI Nov2000

*Based on FFS Medicare Beneficiaries discharged in RI from June 1998-December 1998

measurement relates to women between the ages of 52 and 69 years old; it does not include older women where there may be some concern about the appropriateness of mammograms. We are all aware that convincing some women to get a mammogram can be difficult. The fear of cancer or the anticipation of discomfort associated with mammography can test the most persuasive of physicians. RIQP is working with the breast cancer community to help overcome those barriers with you. We plan to use public service announcements and to talk with women in churches, community centers and libraries. In turn, we need you to encourage your patients to get mammograms. Your word, as her trusted physician, is still the most effective way to convince a woman to get a mammogram.

This is the first report of Rhode Island performance compared to the rest of the country. Does this mean that Rhode Islanders do not receive adequate

care? No absolutely not. Rhode Islanders still receive good care and often, exceptional care. What it does mean is that we have opportunities for improvement. These areas have been identified for us with this report. The data to be used in the next report are being collected right now. If we are going to meet the challenge of improvement set before us, we need to act now.

In our favor is the fact that we are

already working in many of these areas with the hospitals, the Rhode Island Department of Health (HEALTH), The Rhode Island Medical Society

and many other individuals and organizations. Each of our projects in these areas has shown significant improvement. RIQP has had intense discussions with states that have done well to learn the lessons they have to teach us. These lessons are being incorporated into our efforts.

One of the most important lessons I have learned is that many of the most effective ideas for improvement come from the physicians actually in the trenches, those practicing clinical medicine daily. The difficulty is getting to you so we can hear your ideas because you are so busy. We will be holding a series of breakfast forums throughout the state to give us an opportunity to discuss the evidence surrounding these clinical topics and give you the chance to offer your feedback or ideas for solutions. We will also be coming to many of you individually to share your performance rates and give you the same opportunity to provide us with feedback. If RIQP comes to you, we hope you will take a few minutes to share your thoughts and ideas with us. If we do not contact you (there are a lot of you out there!) please contact us. While we have had some successes, now is not the time to rest on our laurels. Our patients are depending on us!

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The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.

Health by Numbers



Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Jay S. Buechner, PhD

Overweight and Obesity Among Rhode Island Adults

Jana E. Hesser, PhD, and Markos Ezra, PhD

Currently, 55% of American adults are overweight or obese according to the new body mass index (BMI) standards established by the National Heart Blood and Lung Institute (NHBLI) in 1998.¹ (see box). In addition, national data indicate that the proportion of Americans who are overweight has been increasing in recent years, with no indication that this trend is slowing.² The most alarming increases have occurred in the percent obese (BMI > 30.0 kg/m²), rising from 12% in 1991 to 18% in 1998.² In 1999, the median rate of obesity for all 54 states and territories was 19.8%.³

New Body Mass Index (BMI) Standards for Overweight and Obesity, for Adults Ages 18 and Older.		
Weight & Obesity Class	BMI* (kg/m ²)	For an Adult 5'7"
Underweight	< 18.5	<118 lbs.
Normal	18.5 - 24.9	119 - 159 lbs.
Overweight	25.0 - 29.9	160-191 lbs.
Obese		
I Mildly Obese	30.0 - 34.9	192-222 lbs.
II Moderately Obese	35.0 - 39.9	223-254 lbs.
III Extremely Obese	≥ 40.0	≥ 255 lbs.

* BMI is defined as weight in kilograms divided by the square of height in meters.

The new weight standards are based on an assessment of the increased mortality risks associated with different degrees of overweight. Mortality rates for overweight/obese persons from all causes, especially cardiovascular disease, are increased 50-100% over those of persons who are not overweight.¹ "Being overweight [or obese], together with poor diet and physical inactivity, is the second leading cause of preventable death in the United States."⁴ In addition, the increased health risks of overweight and obesity translate into increased medical care and disability costs. In 1995 it is estimated that these total costs amounted to \$99.2 billion.¹

Decreasing the number of overweight and obese Americans and preventing the development of overweight and obesity in young people are major public health challenges. This paper examines overweight and obesity among Rhode Island adults based on data from Rhode Island's Behavioral Risk Factor Surveillance System (BRFSS).

Abbreviations Used:

BMI	body mass index
BRFSS	Behavioral Risk Factor Surveillance System
CDC	Centers for Disease Control and Prevention
NHBLI	National Heart Blood and Lung Institute

Methods

The BRFSS is a national telephone survey of randomly selected adults (ages 18 and older) who live in households with telephones. It asks respondents questions about a variety of health-related behaviors, as well as about height and weight. 50 states and 4 territories perform the BRFSS each year with funding and methodological standards provided by the Centers for Disease Control and Prevention (CDC).⁵

A professional survey contractor conducts the BRFSS in Rhode Island. During the years 1991 to 1997, about 1,800 Rhode Island adults were interviewed each year, or approximately 150 per month. For 1998 and 1999 the annual sample size was increased to 3,600, with about 300 interviews conducted each month. The questions on height and weight, used to calculate BMI, have remained unchanged between 1991 and 1999.

Results

The prevalence of obesity among Rhode Island residents increased from 9.7% in 1991 to 16.8% in 1999. The prevalence of overweight increased from 32.7% in 1991 to 37.4% in 1999.

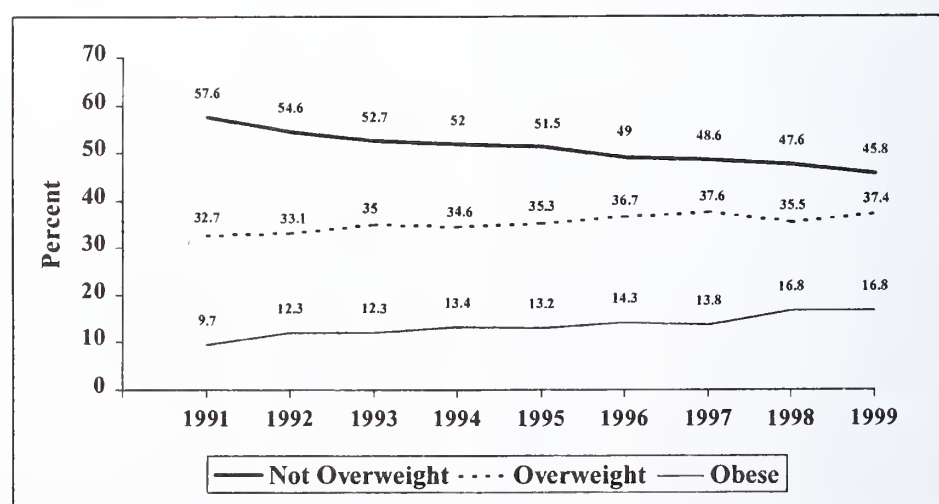


Figure 1. Trends in Weight Status, Ages 18 and Older, Rhode Island 1990 - 1999.

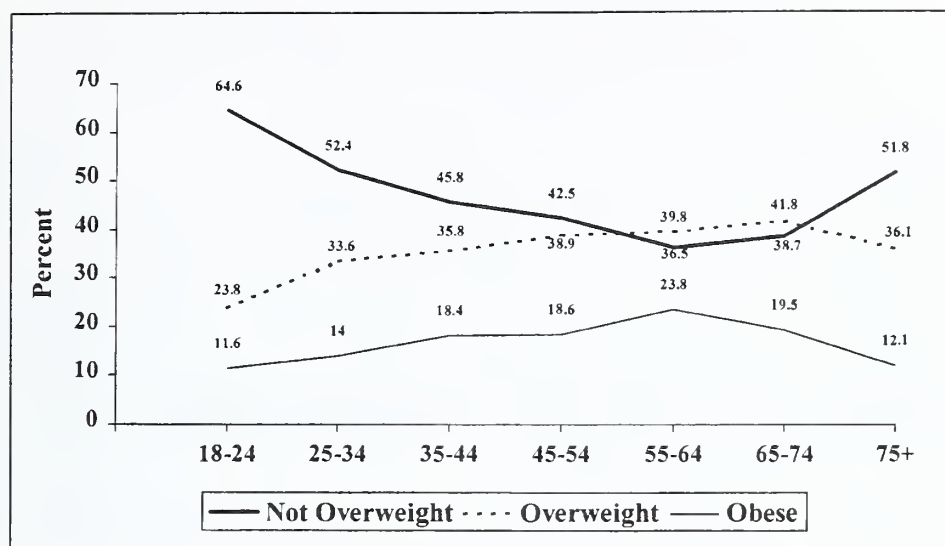


Figure 2. Weight Status by Age, Ages 18 and Older, Rhode Island 1998.

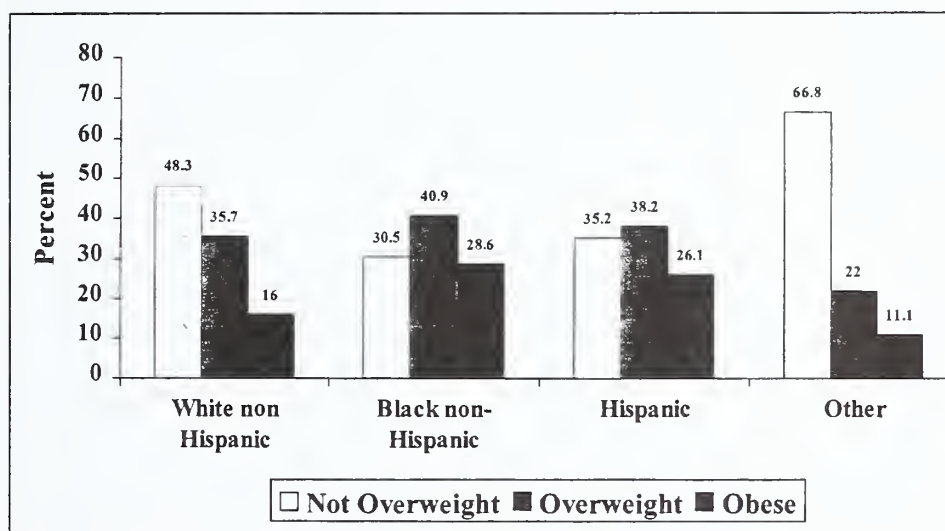


Figure 3. Weight Status by Race and Ethnicity, Ages 18 and Older, Rhode Island 1998.

lence of those who are not overweight declined from 57.6% in 1991 to 45.8% in 1999. (Figure 1) The prevalence of overweight and obesity is higher among males (45.4% overweight, 18.5% obese) than among females (26.2% overweight, 15.3% obese) in Rhode Island. Males ages 55-64 have the highest rate of obesity (25%) of any age/gender group.

There is a strong association between overweight/obesity and age. Overweight increases up to ages 65 - 74, then decreases. Obesity increases up to age 55 - 64 and then declines markedly (Figure 2). The age-related decline in the prevalence of overweight and obesity may reflect the greater risk of premature mortality among such persons, with the obese being at greatest risk of premature death.

There are major differences in overweight and obesity by race/ethnicity (Figure 3). Blacks and Hispanics are more likely than Whites to be overweight (41% and 38% vs 36% respectively), and even more likely than Whites to be obese (29% and 26% vs 16%), respectively. The "Other" race/ethnicity category, which includes primarily Asians and a small number of Native Americans, and Pacific Islanders, has much lower rates of overweight (22%) and obesity (11%) than any other group.

Discussion

Reducing overweight and obesity in the U.S. population will take time, requiring efforts to prevent weight gain among those who are not overweight, and loss of weight among those who are already overweight. Research shows that weight loss is not permanent for the majority of persons who do not lose weight. Consequently efforts aimed at preventing excessive weight gain, especially among children, should be a priority. However, efforts aimed solely at getting people to modify their personal eating and exercise patterns will not be enough. Policy, environmental, and societal modifications must occur as well for people to be able to attain and maintain a healthy balance of calories ingested and expended.

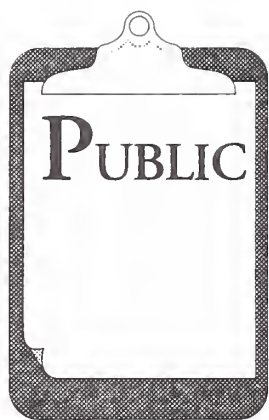
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HEALTH BRIEFING

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by John P. Fulton, PhD

The Safety of Calcium Fortification

Nancy A. Sutton, MS, RD

It has been well documented that increasing calcium intake levels help protect against the development of osteoporosis. The public health messages over the past decade advised people to eat plenty of calcium-rich foods to maintain healthy bones. Supplements are recommended for those who find it difficult, for whatever reason, to get this nutrient through diet. The food industry has jumped on the band wagon. Calcium-fortified foods are on the increase. The public has also responded. Calcium supplements are being sold like never before.

Grocery store items such as orange juice, ready-to-eat breakfast cereals, breads, sparkling water, cheeses, and even milk have added calcium. This has been welcomed by health professionals and the public alike. It will make it easier for busy mothers, difficult-to-feed children and adolescents, and the on-the-go men to meet the recommended Adequate Calcium Intake (AI). But what about the health-conscious person who already meets the AI? Calcium is a threshold nutrient, but how much is too much?

The media has posed this question to the medical community and raised concerns amongst the public. In June 2000, the *Washington Post* published an article questioning the safety of calcium-fortification, "New! Improved! Dangerous?" Specialists were asked about the possible effects of high calcium intakes. Robert Heaney, MD, of Creighton University and Bess Dawson-Hughes, MD, of the Human Nutrition Research Center at Tufts University, both speakers at the National Institutes of Health Consensus Development Conference in 1994, and Richard Wood, PhD, also of Tufts University, are quoted in the article.¹

Dr. Heaney feels there is little to worry about when calcium comes strictly from food, including fortified foods. To make his point, he refers to populations in East Africa and Scandinavia who consume between 6,000 and 7,000 milligrams (mg) of dietary calcium per day regularly without a problem. Drs. Dawson-Hughes and Wood did not agree. Although they recognize that calcium toxicity is rare, they still advised keeping levels below 2500 mg per day.¹

Twenty-five hundred milligrams per day was established by the National Academy of Sciences as the Tolerable Upper Intake Level (UL) for all healthy

Abbreviations Used:

AI	Adequate Calcium Intake
MAS	Milk-Alkali Syndrome
NIH	National Institutes of Health
RDA	Recommended Dietary Allowances
UL	Upper Intake Level

individuals above the age of one year.² As shown in Table 1, with the help of calcium-fortified foods and two supplements per day this level can be easily exceeded.

RISK OF CALCIUM TOXICITY

Calcium toxicity may lead to hypercalciuria, resulting in

Table 1: Sample Menu with Calcium-Fortified Foods

Meal	Food	Calcium
Breakfast:	1 ½ cups of fortified cereal	1500 mg
	1 cup of fortified milk	400 mg
	1 cup of fortified orange juice	300 mg
	1 banana	7 mg
	calcium supplement	300 mg
Snack:	½ cup of yogurt	200 mg
Lunch:	sandwich with fortified bread	360 mg
	and 1 ounce of cheese	400 mg
	1 cup of fortified milk	
Snack:	1 apple	10 mg
Dinner:	3 ounces of calcium-processed	620 mg
	tofu with stir fried vegetables	400 mg
	1 cup of fortified milk	300 mg
TOTAL CALCIUM:		4797 mg

Table 2: Some Commonly Used Calcium Supplements and Their Absorption Rates⁸

Type	Brand Name	Strength per tab (mgs)/ Elemental Calcium (mgs)
Calcium Carbonate (39 ± 3% absorption)	Alka Mints	850/340
	Caltrate	1600/600
	OsCal	625 or 1250/250 or 500
	Rolaids	550/220
	Titralac	420/168
	Titralac Liquid	1000/400
Calcium Citrate (30 ± 3% absorption)	Tums/Tums E-X	500 or 750/200 or 300
	Tums Ultra/Tums 500	1000 or 1250/400 or 500
	Citracal Liquitabs	2376/500
	Citracal	950/200
	Citracal Caplets +D	1500/315 + 200 IU vitamin D

Table 3: Adequate Calcium Intake (AI) ²		
	Age	Calcium Intake Per Day
Both Male and Female:	0 - 6 months	210 mg
	7 - 12 months	270 mg
	1 - 3 years	500 mg
	4 - 8 years	800 mg
	9 - 18 years	1300 mg
	19 - 50 years	1000 mg
Pregnant and Lactating Women:	> 51 years	1200 mg
	14 - 18 years	1300 mg
	19 - 50 years	1000 mg

kidney stone formation (nephrolithiasis) and hypercalcemia. Although these conditions are not considered a major health threat, the current trend to market calcium-fortified foods and self-prescribe calcium supplements has raised concerns. Approximately 10% of Americans will be affected by kidney stones at some time in their life.³ Will this figure rise in the future?

Based on a review of literature published between 1980 and 1996, Whiting and Wood report an increase in case studies of Milk-Alkali Syndrome (MAS) typically seen in the early 1900s. MAS is caused by alkalosis due to prolonged intake of excessive amounts of milk and soluble alkali and is characterized by elevated blood calcium without an increase in calcium or phosphate in the urine (renal insufficiency). Whiting and Wood found several case reports of patients with symptoms similar to MAS. The typical MAS patient at that time had an average daily calcium intake of 20 grams (g) from milk and calcium carbonate. Current cases are showing similar results with daily calcium intakes of between 1 g and 16 g with long-term antacid use, calcium carbonate intake, or the presence of a clinical condition that promotes calcium toxicity (e.g., use of thiazide diuretics, dehydration, alkalosis, or preexisting renal failure).⁴ Recent studies have also shown that low-calcium diets and the intake of supplemental calcium have increased the risk of kidney stones.^{5, 6, 7}

ABSORPTION OF CALCIUM

The human body has a mechanism to help protect it against high levels of calcium intake. The more an individual consumes at once, the less the intestine will absorb.

For example, the 30% absorption rate of milk can be reduced to 15% if consumed with large amounts of highly calcium-fortified foods. With one cup of Total breakfast cereal (1000 mg of calcium) and a cup of milk (300 mg), the amount absorbed would decrease to about 15%. Of the total 1300 mg, a total of 195 mg is being absorbed, versus the 390 mg one may have expected.

The amount of calcium absorbed is also affected by its source, and can range tremendously. For instance, approximately 30% of the calcium in milk and other dairy products is absorbed, whereas it can be as low as 5% from fruits and vegetables. Only 7 mg of the 129 mg (5%) of calcium found in one-half cup of spinach is absorbed. Therefore, although a person can meet calcium needs without milk or milk products, it may be difficult.

Calcium supplements are a nondietary, alternative source

of calcium with absorption varying from 27% to 39%. Table 2 lists commonly used calcium supplements and their absorption rates.

CURRENT RECOMMENDATIONS

Table 3 provides the AI for calcium defined by the National Academy of Sciences in 1997. These recommendations were based on varying absorption rates of calcium sources and patterns of consumption. The AI replaces the Recommended Dietary Allowances (RDA). The recommendations for most age groups were increased based on scientific evidence showing that the higher calcium intakes reduced the risk of osteoporosis.² The AI and the UL apply to individuals susceptible to kidney stone formation as well.^{5, 6}

The 1994 National Institutes of Health (NIH) Consensus Statement on Optimal Calcium Intake points out the risks involved with calcium. Although the body protects itself against calcium toxicity by reducing the percentage absorbed by the gut during periods of high intake, this is only so effective. The NIH indicates that once the daily intake levels exceed 4 g, toxicity may result. They also discuss the dangers of these levels being reached due to the "overuse of calcium carbonate, in the form of antacids." They conclude that calcium intakes above 2,000 mg per day should be monitored closely.⁹

Whiting and Wood agree that the 2,000 mg limit set by the NIH in 1994 was justified. They address the issues of excessive calcium through fortified foods and through supplements and antacids. Although the development MAS and kidney stone formation is not presently considered a public health threat, there is still a concern with some individuals who are at a high risk of developing either one of these conditions. Based on the increase in calcium-fortified foods and the use of calcium supplements and antacids, they recognize a need for more research in the area of calcium toxicity.⁴

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CONCLUSION

Although the number of case reports of calcium toxicity remains relatively low, there is a consensus among researchers to keep total calcium intakes below 2500 mg per day. The use of calcium supplements and calcium-containing antacids should be monitored among patients who are already consuming adequate amounts of dietary calcium and those at risk of stone formation. Because we lack study results determining the safety of high dietary calcium intake related to calcium-fortified foods, health professionals should monitor all sources of calcium to help prevent possible adverse effects.

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Judicial Diagnosis

Physician "De-selection:" Healthcare Providers' Rights When Terminated From Managed Care Plans

Lawrence W. Vernaglia, JD, MPH

Suppose the morning mail brought you a letter from a managed care organization (MCO) representing a substantial portion of your practice, stating that you must either join a new "practice unit" of the MCO - which significantly alters the risks and profitability of treating the MCO's members - or else be terminated as a provider under the plan. What could you do?

Rhode Island doctors have witnessed a lull in MCO "de-selections" (industry jargon for when an MCO terminates its managed care contract with physicians or other providers) and network-narrowing efforts over the past 5 or 6 years.¹ However, this past year's liquidation of Harvard Pilgrim Health Care plan and the ancillary receivership of Tufts Health Plan of New England in Rhode Island, as well as increased rumblings from other Rhode Island health plans about "limited networks," demonstrate that physicians are not insulated from the rough-and-tumble disruptions in the managed health care environment. As Rhode Island MCOs continue to subcontract with physician groups willing to bear financial risk, local providers may experience a wave of de-selections as MCOs attempt to push more of their physicians into risk-bearing "practice units," "access units" or similar entities. This essay will address recent examples of health plans de-selecting physicians and examine how these issues are being resolved, both regionally and in Rhode Island.

In July 1999 Tufts Health Plan sent the letter described at the top of this article to a number of primary care physicians in Massachusetts. These doctors could either join one of the Tufts "practice units" or face de-selection by the MCO. Once de-selected, their MCO patients would be referred to other physicians who consented to join a Tufts practice unit. The termination of the physicians was apparently in compliance with the express terms of the physicians' contracts with Tufts.

The Massachusetts Attorney General stepped in to protect the patients/beneficiaries from having their physician relationships suddenly disrupted. The Attorney General and Tufts entered into an "Assurance of Discontinuance" on Janu-

Abbreviations Used:

JCAHO	Joint Commission on Accreditation of Healthcare Organizations
MCO	managed care organization
NCQA	National Committee for Quality Assurance

ary 27, 2000, under which Tufts agreed to rescind the letters and permit the patients to continue seeing their physicians throughout the remainder of the patients' contract year.² The Assurance of Discontinuance did not, however, guarantee that these physicians would be paid for treating their Tufts' patients after December 31, 2000.

Clearly the Commonwealth was not interested in protecting the physicians but, rather, the patients/beneficiaries. This cautionary tale demonstrates that while state government may take actions that prevent managed care companies from arbitrarily terminating physician/patient relationships, the government's primary interest is not protection of the doctors. As local MCOs push to contract only with sub-capitated, risk-bearing providers, Rhode Island physicians should be prepared for similar overt pressures from health plans. Thus, physicians must be vigilant when contracting with MCOs.

Rhode Island law and Department of Health regulations protect physicians from certain terminations by managed care companies. In particular, health plans may not:

- refuse to contract with, or compensate, a physician who is otherwise eligible to participate, solely because the physician has in good faith communicated with one or more of his or her patients regarding the provisions, terms, or requirements of the health plan as long as they relate to the needs of that physician's patient;³
- terminate a physician "without cause," or write contracts with physicians that appear to allow the plan to terminate

the contract "without cause";⁴

- exclude a physician from participation in its provider network solely based on the degree or type of license, or lack of affiliation with, or admitting privileges at, a hospital, if such lack of affiliation is due solely to the type of license;⁵
- terminate a physician solely because the physician treats a substantial number of patients who require expensive or uncompensated care.⁶

The regulations, however, do permit managed care companies substantial discretion in ending relationships with physicians against the wishes of physicians and their patients. For example, nothing prohibits MCOs from forming limited networks of physicians. Moreover, despite the prohibition of terminations "without cause," a health plan may terminate a physician for "lack of need due to economic considerations."⁷ This rule has spawned considerable confusion. MCOs may, at least under the regulations, employ "economic profiling" of physicians (credentialing based on practice patterns, utilization, case mix of the physician's patients, severity of the illness of those patients, patient age and "other features of a professional provider's practice that may account for higher than or lower than expected costs").⁸ The regulations permit a health plan to "make changes to a physician's contract" so long as the physician has an opportunity to amend or terminate the contract as a result of the proposed changes within sixty (60) days of the physician's receipt of the notice of the changes.⁹ Since powerful MCOs rarely permit amendments, physicians are left with the limited remedy of termination. Where the plan represents a substantial portion of a physician's practice, termination may be a hollow remedy. Finally, the regulations permit a watered-down "due process" if a health plan denies a physician's application, though the regulations do not clearly require due process for de-selections.¹⁰

What do these regulations mean, on balance, to physicians? Although the rules provide some minimal degree of protection for physicians from de-selection actions in Rhode Island, the system is designed to protect patients, and benefits the managed care industry far more than the physicians. Physicians aggrieved by what they have perceived to be arbitrary or capricious de-selection in other New England states and nationally have sued, with mixed results, claiming that the MCOs' de-selections violated public policy or the implied covenant of good faith and fair dealing.^{11,12}

Nothing prohibits a physician from negotiating or modifying a managed care contract to provide greater protections than the minimum established under Rhode Island law. As with any business, the ability of the physician to negotiate terms of a managed care contract depends on the relative bargaining powers of the parties. Physicians with large practices,

needed specialties, or geographic distribution are better able to demand reasonable protections under their contracts with MCOs than other physicians.¹³ Contracts with negotiated protections for the physicians are more difficult for MCOs to terminate at will without the risk of severe sanction and damages in courts or arbitration proceedings.

An additional systemic protection for Rhode Island doctors is due to the small, yet diverse, population in the State. Plans that are overly aggressive in de-selecting physicians for economic or utilization management purposes, or just to limit

networks, may create immediate access problems. As in Massachusetts, the Rhode Island Department of Health would likely intervene in such cases for the protection of the members' access to providers.

In summary, while the government may be available to provide minimal assistance in the face of large-scale physician de-selections, the regulations and authority of state agencies will be of minimal utility to the physician community in most cases. Consequently, physicians negotiating and renewing their managed care contracts should protect as much as possible against arbitrary de-selection and disruption of longstanding physician-patient relationships.

ACKNOWLEDGEMENT

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"access units" or similar
entities.*



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3. R23-17.13-CHP-5.1.
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10. The major health plan accreditation bodies (such as the National Committee for Quality Assurance (NCQA) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) require MCOs to provide physicians with "due process" regarding a de-selection. Some of these procedures are more protective of physicians' rights than the minimum under state law. Therefore, doctors should review a particular plan's accreditation standards in connection with any attempts to access an MCO's appeal procedures.
11. See *Harper v. Healthsource*, 647 A.2d 962 (N.H. 1996) (In New Hampshire, "public interest and fundamental fairness" demand that an MCO's decision to terminate a contract with a physician must meet the threshold covenant of good faith and fair dealing and not be for reasons that violate public policy because "[t]he

public has a substantial interest in the relationship between health maintenance organizations and their preferred provider physicians”); see also, *Napoletano v. Cigna Healthcare of Connecticut*, 680 A.2d 127 (Conn. 1996) (holding that physicians could bring actions in the Connecticut courts against a health plan for de-selection).

12. Other courts have held that appeal procedures after de-selection must be “substantively reasonable and procedurally fair,” and the common law right to fair procedure applies if the MCO’s power is so substantial that “the removal [of the physician from the panel] significantly

impairs the ability of an ordinary, competent physician to practice medicine or a medical specialty in a particular geographic area” *Potvin v. Metropolitan Life Insurance Company*, 497 P.2d 1153, 22 Cal. 4th 1060, 2000 WL 554891 (May 8, 2000).

13. Sometimes small practices have made significant changes to MCO contracts before signing and return the document to the MCO. If the MCO does not object to the revisions, and commences performance (payment for services), then the physicians have a good argument that the changes were accepted by the MCO.

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Letter to the Editor:

In a recent article [August 2000] Max Wistow and Rachael Arruda suggest that medical malpractice tort actions provide two benefits: compensation for the victim of medical malpractice, and a reminder to the health care professional of the legal consequences of negligence. Their article, however, disproves both of these conclusions. As they state, most cases of negligence are not accepted by malpractice attorneys because the monetary value does not justify the investment of time and effort by the malpractice attorney and the appropriate consultants. Thus, even though loss of earnings on a modest level might not justify a malpractice suit, those earnings might be very significant to a person of modest resources. The majority of patients, who have only limited injury in terms of the ability to recover money, get nothing whatsoever from the tort system.

Indeed, the doctor who has acted negligently and whose negligence has resulted in a large monetary recovery does get reminded dramatically of the consequences of his or her negligence. On the other hand, the vast majority of negligent acts produce either no injury, or minor injury. They do not result in legal action and do not generate a reminder.

Doctors have an ethical responsibility to report medical mistakes to the patient, particularly when there has been, or could be, a change in the care of the patient. In fact, it is to the doctor’s legal disadvantage to report such negligence to anyone. The legal consequences of such reporting may deter the doctor from fulfilling his or her ethical responsibility. In those cases which do not result in legal action the doctor may continue a pattern of suboptimal practice. Even in those few cases with great potential monetary damages, the potential harm to other patients is not addressed immediately, as the doctor

may continue to practice while the legal case drags on for many years.

Patients and the public would be better served by a different system, one which separates punishment of the physician from the reporting of medical mishaps. Such reports should be made in the context of a continuous quality improvement system without the fear of legal consequences. Such a system would review all medical errors, major and minor, and address ways of preventing recurrences. Medical malpractice cases could still be filed but they would be independent of the quality improvement system and the data from such a system would not be available to the plaintiff. This system might also address the issue of compensation for those patients who do not have injuries sufficient to trigger a formal legal action.

Herbert Rakatansky, MD
Clinical Professor of Medicine
Brown University School of Medicine

Response:

The potential of being on the wrong end of a large malpractice award *does* operate as a substantial incentive toward avoiding negligence. Since virtually all acts of negligence in the medical/surgical context have the potential for a catastrophic result, a doctor cannot know, *a priori*, that the result will be no injury or only a modest one.

It is certainly true that our present system offers little or no opportunity for compensation to the victim of malpractice if the injury is relatively small. That defect, however, is one that I would expect few health care practitioners to seek to remedy. If the medical community can come up with a system to compensate such people, it will be embraced with enthusiasm by legions of lawyers.

Dr. Rakatansky’s anodyne “contin-

ous quality improvement system without the fear of legal consequences” is devoutly to be wished. We already have in place peer review, M&M conferences, quality care reviews and the like, all shielded from disclosure in malpractice suits. His statement that “the public would be better served by a different system” acknowledges the failure of peer review. We all know that the doctor who is caught up in the process is most often one who is unpopular. Those who haven’t stepped on too many toes will be protected within and by the system. The recent case of serial killer Michael Swango, MD, proves that the medical establishment is quite capable of letting a doctor get away with murder. Literally. Confronted with eyewitness reports that Swango had tampered with a patient’s IV and nearly killed her, he was allowed to complete his internship by Ohio State College of Medicine. Later, after being convicted of poison-

ing co-workers, he was accepted into a residency in Internal Medicine.

An extreme case? Undoubtedly. Nevertheless, it is merely one end of the spectrum displaying the inability, nay, unwillingness, of the medical profession to police itself. In our own experience, we have encountered numerous instances of shocking inaction and cover-ups to protect the malpractitioner and where but for the civil suit brought, no restrictions would ever have been put in place.

Our present system is flawed. Yet it is by far the best we have.

Human nature has not changed since the 17th century when John Donne noted that one must “observe the physician with the same diligence as he the disease.”

Max Wistow, JD
Rachael Arruda, RN



Vital Statistics

Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report

Provisional Occurrence Data
from the
Division of Vital Records

Underlying Cause of Death	Reporting Period			
	Nov. 1999	12 Months Ending with Nov. 1999		
Diseases of the Heart	237	Number (a)	Rates (b)	YPLL (c)
Malignant Neoplasms	187	2,957	299.1	3,970.5
Cerebrovascular Diseases	46	2,479	250.8	6,807.0
Injuries (Accident/Suicide/Homicide)	18	542	54.8	631.5
COPD	28	378	38.2	6,902.5
		492	49.8	342.5

Vital Events	Reporting Period		
	May 2000	12 Months Ending with May 2000	
	Number	Number	Rates
Live Births	1,282	13,008	13.2*
Deaths	806	10,024	10.1*
Infant Deaths	(16)	(106)	8.1#
Neonatal deaths	(13)	(89)	6.8#
Marriages	805	7,813	7.9*
Divorces	323	2,793	2.8*
Induced Terminations	423	5,224	401.6#
Spontaneous Fetal Deaths	91	1,096	84.3#
Under 20 weeks gestation	(89)	(1,027)	79.0#
20+ weeks gestation	(2)	(69)	5.3#

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 988,480

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population

Rates per 1,000 live births

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NINETY YEARS AGO

❧ [NOVEMBER, 1910] ❧

Noting the "timely connection" in the opening of the John Hay Library at Brown and the proposed new Medical Society Library, an editorial praised the John Hay ("commodious and indestructible. The stack...is in immediate access to reading and working rooms"), even while critiquing its edifice ("too coldly grand") its "overlighted" reading room ("contrary to the belief that too much light is an impossibility") and its lack of "literary hospitality." "A library may lure you to enter, but it must somehow invite you to remain, else it becomes a mere cold storage of printed things."

In "Treatment of Infantile Paralysis," Frank E. Peckham, MD, argued against swabbing out the nasopharynx with a solution: "...those of us who remember the treatment of diphtheria by such means, the holding between the knees the head of a struggling, screaming, yelling, squirming child will at once recognize the futility of any such procedures." He urged colleagues to assess the condition of muscles ("The old idea was to make electrical tests, but...it is far better to get the patient to make active motions with all the muscles in turn"), then treat selected muscles with "a proper vibrator, which not only stimulates beautifully the nerve and circulatory supply, but fills the muscular tissues with blood..."

FIFTY YEARS AGO

❧ [OCTOBER, 1950] ❧

In "Metastatic Krukenberg Tumor of the Ovary, Primary in the Breast, with Six Year Survival," Henry C. McDuff, MD, noted that Krukenberg's original description of the tumor ("primary in the ovary, and classified as a sarcoma") was found incorrect, "but his cellular description remains a classic." Currently many physicians considered the Krukenberg tumor metastatic, while others disagreed, just as physicians disagreed on the site of the primary neoplasm. The author "...believed them to be malignant tumors of the ovary, primary, or metastatic from any focus." In the case of a 44 year-old Russian-born female, who had had a radical right mastectomy, followed by x-ray treatment, three years earlier, Dr. McDuff traced the progression. She developed metastatic lesions in the neck of the left scapula, prompting more radiation therapy. Still later she received radiation therapy for the mass of skin metastases over her anterior chest wall and right parietal region of head. She started on testosterone therapy, then returned with an ovarian tumor. One

year later she was "now apparently enjoying excellent health and was free of symptoms."

Robert V. Louis, MD, and Louis I. Kramer, MD, offered a case report: "Serum Protein, Cephalin Flocculation and Thypnol Turbidity Alterations in Lupus Erythematosus Disseminatus."

William J. Schwab, MD, offered a case report: "Use of Testosterone in Breast Cancer." A 63 year-old woman, with inoperable breast cancer, was treated with testosterone, starting with 200 mg, increasing steadily. At 3000 mg, the patient's voice had deepened, and she had developed "a slight but definite growth of [facial] hair, but "she stated she felt much better." The authors called hormone therapy "a last resort."

An Editorial on "Convalescent Homes" criticized the Providence Building Inspector for his warning to close nursing homes, and refuse them licenses, "should they fail to be of brick structure above the first floor." The editorial proclaimed, "We cannot recall any serious injury to people caused by fire in wooden hospitals or convalescent homes of this city."

TWENTY FIVE YEARS AGO

❧ [OCTOBER, 1975] ❧

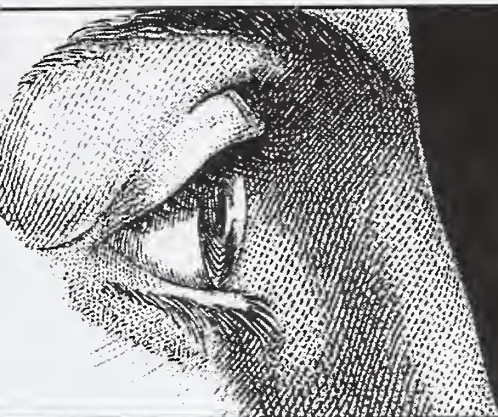
On the "President's Page," Stephen J. Hoyer, MD, urged readers to heed three recent newspaper headlines: 1) RIGHA purse boosted \$2.4 million; 2) HEW Regulations deny free choice of physician if unions elect an HMO; and 3) Private carriers cost of handling health claims is almost one-quarter of Social Security Administration. The headlines proved that "the medical profession is the first to come under federal regulations."

In "Surgical Revascularization for Patients with Unstable Angina Pectoris: Surgical Treatment," K.E. Karlson, MD, A. S. Most, MD, G.N. Cooper, Jr., MD, R.S. Riley, MD, K.B. Nanian, MD, R.D. Raymond, MD, R. J. Capone, MD, C.W. Cashman, MD, and L.L. Vargas, MD, described the results of aortic coronary bypass in 24 patients: one died during the operation, 83% were free afterward of the angina.

In "An Antibiotic Update: New Aminoglycosides and Other Antibiotics," Phillip J. Rubin, MD, and Stephen H. Zinner, MD, cautioned: "The use of new potent antibiotics [e.g., streptomycin, neomycin, kanamycin, gentamycin] should be limited to clear-cut indications."

Mary D. Lekas, MD, FACS, in "Gardiner's Syndrome and Nasal Obstruction," reported on 6 affected males from one family.

Hector Jaso, MD, in "The Battered and Abused Children Act of the State of Rhode Island," alerted readers to the law: physicians must report suspected abuse or battery.



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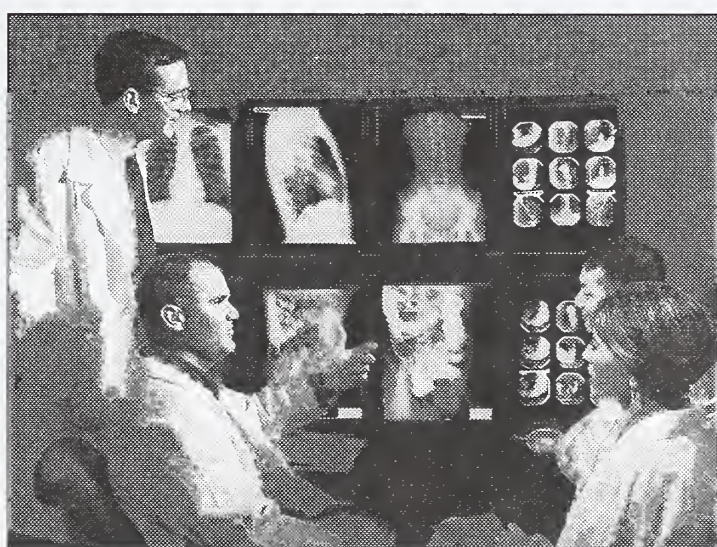
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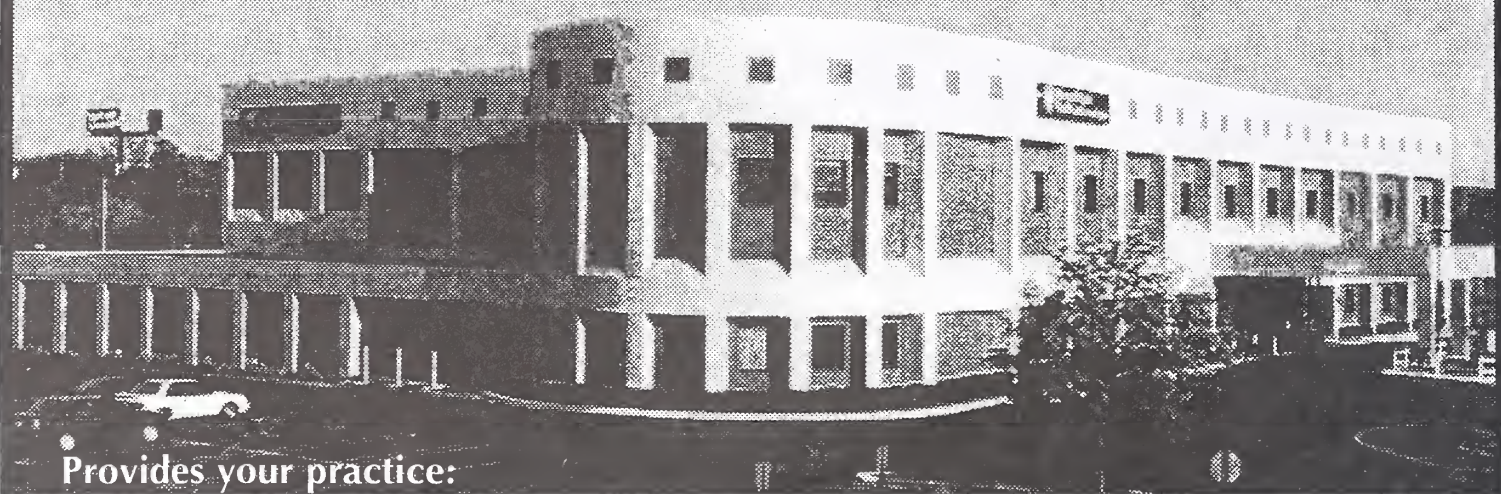
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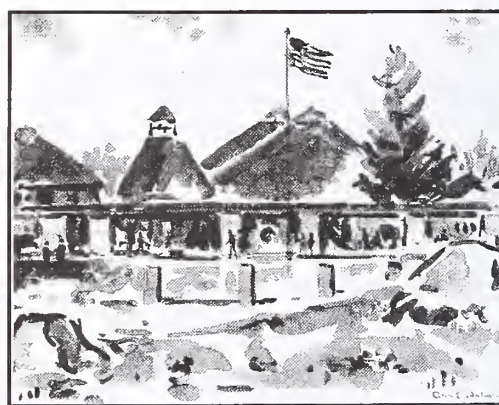
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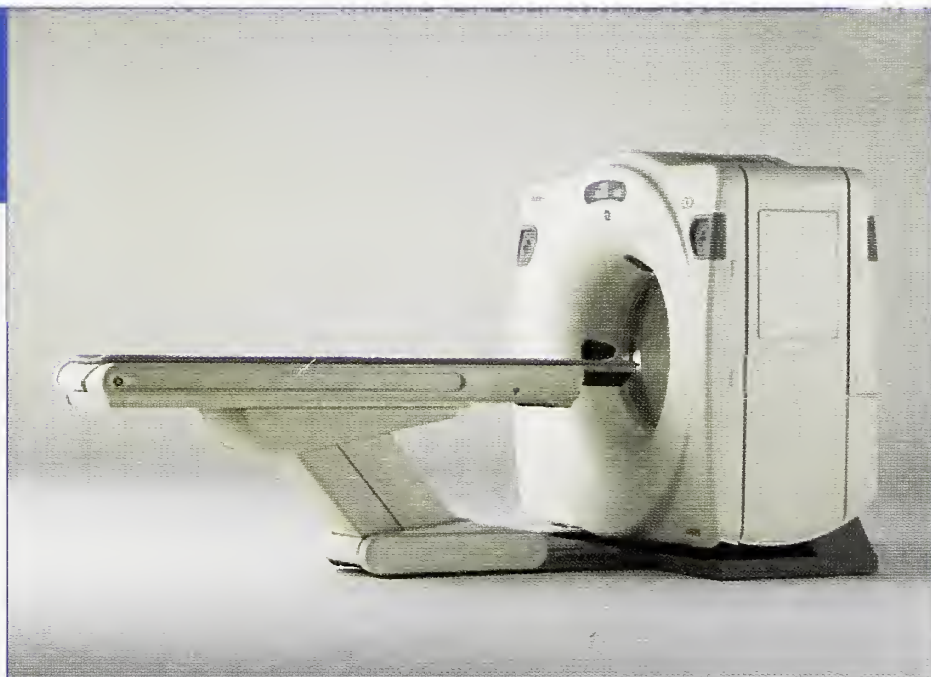
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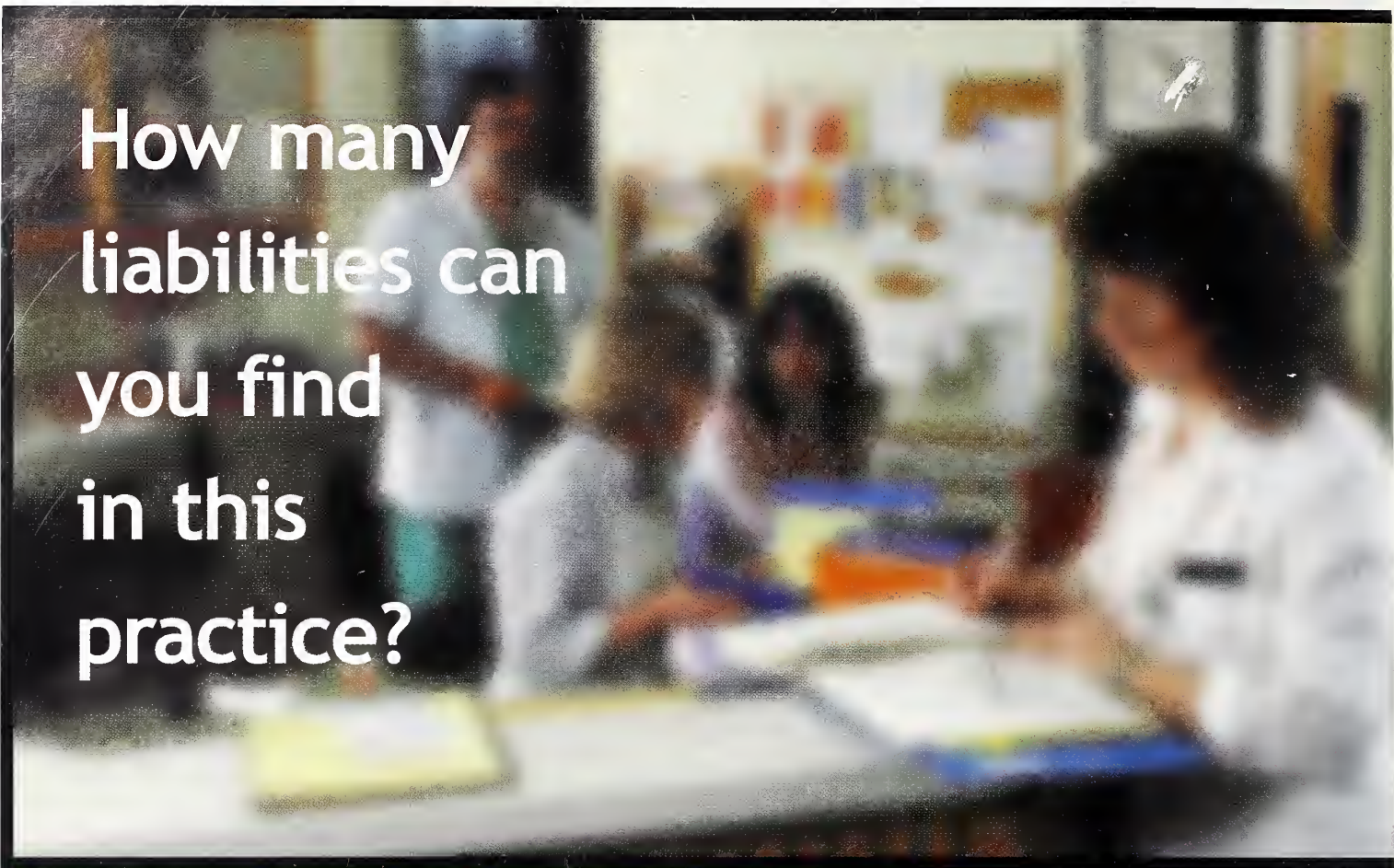
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Prison Clinical Trials

An eminent ethicist read the manuscripts in this issue and decided he was not sufficiently versed in the field to venture a critique or overview of these articles. The authors include Dr. Anne De Groot, the guest editor, one of the finest laboratory scientists at Brown University, and Nancy Dubler, from Albert Einstein College of Medicine. Ms. Dubler is a lawyer who has become a prominent ethicist. Even though I claim no expertise, as the editor I feel the need to point out the issues I consider important to the general reader. Fools venture where angels fear to tread.

If I read these papers correctly, they pose two fundamental questions: Is this one type of "undue influence" or "positive" coercion? And when does coercion cross the line from ethical to unethical? The basic postulates are that: a) health care for prisoners with AIDS is substandard; b) the quality of medical care in any American-run AIDS clinical trial will equal and most likely far exceed that available to prisoners even for subjects randomized to the placebo arm of a study; c) prisoners themselves welcome these trials.

On the face of it there doesn't appear to be much of a problem. Prisoners may choose to participate and receive enhanced medical care, or not, in which case they probably get their usual (poor) care. Is this a real choice? Does a drowning man have a choice if offered a life preserver but told he must give up his firstborn? Supposing the prison authorities have no vested interest one way or the other, then the choice is the prisoner's. But what happens to the ethical balance if the prison gains something from each subject, perhaps a small monetary commission (especially in a for-profit prison and a corporate-sponsored trial) or just the

eased burden of spending less per year on drug costs and medical fees? What if the prison decides to make life less comfortable for eligible prisoners who refuse to participate? What if there is petty, or not-so-petty harassment? Surely these scenarios would make trials unethical since prisoners would in fact be coerced to participate. If we return to the hypothetical scenario of a prison with absolutely no interest, one way or the other, in what decision a prisoner makes, is it coercive to choose between substandard vs excellent care?

Our contributors, who have given great thought to this question and to trying to improve the lives of prisoners, think this is not coercive and support the concept of trials in prisons. But one can ask if they themselves can judge. Do they benefit from the trials? Do they get more publications, more research dollars for other projects, higher preference for the next commercially underwritten AIDS study? In the case of Dr. De Groot, for example, this is clearly not the case. She is a laboratory researcher and her career advancement would be slowed, not advanced, by a foray into clinical trials in prison. Her participation should be seen as altruistic. This journal issue then is an attempt to ethically justify this venture.

The reader should keep in mind that phase 1 and phase 2 trials are not allowed. This eliminates the first pass risk aspect of a clinical trial. Only after the safety questions have been addressed can these trials proceed.

These authors have not addressed the issue, however, of what constitutes "undue influence." Could trials include payments for non-participants? Could potential subjects fill out anonymous questionnaires designed to find



out why they are volunteering for the study? Perhaps an independent review board could review these questionnaires and decide whether "undue influence" was forcing participation.

There are two further points I wish to make, and readers are welcome to contribute their own thoughts. The first is "scientific." The prison population is special in that compliance may be enforced. Study results then may more accurately assess drug response than a typical outpatient study; but a guaranteed compliance rate, similar to observed therapy in TB treatment, may not extrapolate to the non-imprisoned population. The merits of this approach may be debated and are not necessarily bad. This population may then be of special interest to corporate sponsors wishing to demonstrate drug efficacy. Which brings me to the second point, the "slippery slope" argument. Assuming that the AIDS trials discussed are ethically acceptable, possibly ethically "mandatory," there must be extreme awareness of the possibilities for less well-intentioned parties to begin studies using prisoners in less ethically sound studies both for AIDS and other conditions.

The authors of these articles are to be commended for jumping into the fray and raising our consciousness, whether we agree or not. I lament the observation of Dr. De Groot that the only prison AIDS studies currently under review are those operating under the strict federal guidelines of the OPRR and the studies not so well overseen have escaped this oversight.

— Joseph H. Friedman, MD

The Blessings and Hazards of Prophecy

“The studio was filled with the rich odour of roses, and when the light summer wind stirred amidst the trees of the garden there came through the door the heavy scent of lilac, or the most delicate perfume of the pink-flowering thorn.”

Thus begins Oscar Wilde’s “The Picture of Dorian Gray.” Romantically inclined readers will sigh visibly and respond to the imagery with enthusiasm. But practical readers may be dismayed that no barriers intervened between the feral exterior and the civilized interior. Admittedly, the mosquito population in turn-of-the-century England was negligible when compared with New England. But were there no screens to keep the other summer insects from sharing the interior of the house with humans?

The late 19th Century witnessed a profound improvement in the health and longevity of Europeans and North Americans. Some of these gains reflected better housing and more abundant food; and some can be ascribed to vaccines and antisera against smallpox, diphtheria, typhoid and rabies. But the major forces contributing to this health advantage came through a better understanding of the kinetics of communicable disease. These contributions included the development of effective sewage systems, protected sources of drinking water, invention of the flush toilet, and screening, both cheap and durable, which allowed the aromas of verdant summer to enter the drawing room while excluding disease-bearing insects.

Screens come in various sizes, degrees of porosity and purpose. Some serve merely as decorative partitions, dividing one space from another. And then there are skin ointments which screen out the damaging ultraviolet sun rays. All screens seem to have one common feature: they block certain things but not others. The obstructed object might be an unwanted view, a damaging sun ray or a biting insect.

Medicine has now inverted the meaning of screening to describe diagnostic procedures which identify persons who are likely to have, or to develop in the near future, a particular disease. A medical screen, then, functions more as a capturing dragnet than as an excluding screen.

Medical screens are rapid, relatively cheap triage procedures used to detect disease among apparently healthy populations. A positive test does not provide absolute assurance that the disease exists, merely that the likelihood is very high. Only when a test is positive will a more expensive, more precise test be performed. In the real world screening becomes a compromise between the ideal and reality.

Most systemic diseases begin in silence. Then, for a variable interval [in the case of some cancers, years] the disease progresses insidiously until finally it produces symptoms reflecting internal dysfunction. The time between the biological onset of the disease and the time it finally becomes externally evident is called the latent, or subclinical, interval. It is during this interval, when no warning symptoms have as yet arisen, that screening, a vital component of preventive medicine, becomes most effective.

The development of screening tests rests upon the unvoiced presumption that the detection of a disease in its earliest phases

increases the likelihood of cure and allows for the rapid deployment of public health measures. But there are still illnesses where medicine has neither cure nor even interventions to slow its progress. Screening for such rare diseases will only bring added months of anxiety and dismay to those told that they are victims of an incurable, inexorable disease. Screening therefore requires that it be used judiciously and compassionately.

And screening, with all of its obvious benefits, creates still further problems. All tests, but particularly screening tests, produce a small percentage of inaccurate results. Test results, ultimately, will have divided those tested into four defined populations. The vast majority are in the category of the truly negative. Then there are the true positives, typically about 1%, with the underlying disease then verified by more precise tests. There are two further groups. Those who initially test positive but with more specific tests are shown not to be positive [the false positives]. And those who test negative but in reality harbor the early phases of the disease in question [the false negatives].

Consider now the ramifications of being a false positive or a false negative. If falsely labelled positive, one endures the customary anxieties before eventually finding out that the screening test is inaccurate. And worse, if one is a false negative, one merrily goes on with a mistaken sense of security while a disease such as cancer silently advances. Screening tests that produce a significant percent of false negatives and false positives are customarily discarded.

Medicine also uses the word screening loosely in forensic settings: testing for illegal performance-enhancing drugs, psychoactive chemicals, nervous system depressants in comatose emergency room patients, and for the rapid identification of poisons in children who may have swallowed some household chemical.

Screening for inapparent disease, however, need not always be chemical. Mammography, employing x-rays, has proven to be of immense help in detecting early - and therefore curable - breast cancer. The five-year survival rate has risen dramatically in the last few decades. The screening test might be a microscopic examination such as the Pap test for cancers of various sites, particularly the uterine cervix.

Screening procedures can even identify currently healthy individuals who bear certain inherited traits which may manifest themselves, decades later, as genetic disease. Indeed, when the elements of the human genome are revealed in the next few years, DNA analysis of newborn infants may eventually predict whether such afflictions as cancer, diabetes or Alzheimer’s disease will await them in adulthood.

There are some who do not wish to have access to this information. Each day offers enough worries, they contend, without adding the less savory aspects of the future. After all, these tests predict only bad things and are silent on whether the person tested will win a future lottery. And there are still others who worry lest such predictive information may become public knowledge, thus abridging the privacy and civil liberties of those whose screening tests prophesy a grim destiny.

– Stanley M. Aronson, MD

Clinical Trials in Correctional Settings:

Proceedings of a Conference Held In Providence, Rhode Island, October 13-15, 1999

Introduction

Anne S. De Groot, MD, Elizabeth Hannah Jackson, Elizabeth Stubblefield

Participation in clinical trials can provide prisoners with access to innovative treatments and improve their care. However, research that involves prisoners is legally restricted and ethically problematic. An elaborate system of regulations and professional prescriptions is in place to protect prisoners, who, by virtue of their captivity, are an especially vulnerable class of human research subjects. The unique problems and opportunities that result from the large number of HIV-infected prisoners require researchers and clinicians to reconsider how the current regulations can be applied to prisons. It is essential that protections against abuse remain strong. At the same time, it is critical that we craft a legal framework to promote the ethical conduct of research, allowing prisoners to benefit from the possible therapeutic effects of innovative treatments.

With this in mind, a group of HIV care providers who work in correctional settings organized a conference on the conduct of clinical trials - partly in response to unpublished reports citing an increase in clinical trials in those settings.

Conference organization and participation

On October 13-15, 1999, correctional medical experts, legal experts, ethicists, and prisoner advocates attended the "Clinical Trials in Correctional Settings Conference" organized by the Brown University AIDS Program's HIV Education/Prison Project and Yale University (HIV in Prison Project and Center for Interdisciplinary Studies on AIDS). The goals were to examine the history of trials in correctional settings, to review medical, legal, and ethical guidelines for the conduct of clinical trials, to hear about ongoing trials and to propose expanded guidelines which would enable inmates

and their HIV providers to have access to experimental therapies, while protecting inmates from potential abuses of clinical research.

Conference organizers were Anne S. De Groot, MD, Director of the TB/HIV Research Lab at Brown University and Co-chair of the HIV Education/Prison Project (HEPP) at the Brown University AIDS Program, David Thomas, MD, JD, Medical Director of the Florida Department of Corrections (DOC), Frederick A. Altice, MD, of the HIV/Prison Project at Yale University, and Al Novick MD, of the Center for Interdisciplinary Studies on AIDS at Yale. Additional organizers included David Wohl, MD, of University of North Carolina, David Paar, MD, of Texas UTMB and Director of HIV care for the Texas DOC, Joe Bick, MD, of the California DOC, Betty Ryder, of the NC DOC, Ned Heltzer, of PHS, Lou Tripoli, MD, of CMS (central office) and Ken Mayer, MD, Director of the Brown University AIDS Program. The conference was sponsored by the HIV Education Prison Project at Brown and supported by unrestricted educational grants to HEPP at the Brown AIDS Program by ten manufacturers of HIV medications (Abbott, Agouron, Bristol Meyers Squibb, Glaxo Wellcome, Hoffman LaRoche, Gilead, DuPont, Merck, OrthoBiotech, and Roxane).

Organizers and participants recognized the linkage between advances in medical treatment and the conduct of medical research. Many participants were "hands-on" providers of HIV care, familiar with the conduct of clinical trials for AIDS research in the community, who wished to provide equal

Abbreviations Used:

ACTG	AIDS Clinical Trials Group
AIDS	acquired immune deficiency syndrome
CDC	Centers for Disease Control and Prevention
DOC	Department of Corrections
FDA	Food and Drug Administration
HEPP	HIV Education/Prison Project
HIB	human immunodeficiency virus
IDU	intravenous drug user
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
OPRR	Office for the Protection against Research Risks

access to research benefits for their incarcerated patients. Many researchers (clinical trialists) and pharmaceutical company representatives attended the conference, as did representatives from the Centers for Disease Control and Prevention (CDC), the Office for the Protection against Research Risks, (OPRR, now the Office for Human Research Protections or OHRP), and the National Institutes of Health (NIH). Representatives from the Federal Drug Administration (FDA), which regulates clinical trials that are not funded by a federal agency (such as trials conducted by the pharmaceutical industry), were invited but did not attend.

It was clear from conference reports that clinical trials in correctional settings had been, and were being, conducted. Some of the studies reported at this conference were funded by the NIH through the AIDS Clinical Trials Group. Human studies components of these studies would be regulated by the OHRP. Other trials were funded and carried out by the pharmaceutical industry; human studies components of these trials would normally be regu-

lated by the FDA. Researchers (both academic and industrial) have been actively seeking out correctional research partners. It was not clear whether government regulatory agencies were aware of the number of trials, past or current, in correctional settings.

The number of trials, moreover, has increased because the number of inmates affected by HIV, TB, and hepatitis C has increased. The number of inmates affected by HIV is 5 fold higher than the number in the general population. Tuberculosis case rates are five to twenty times higher; hepatitis C case rates are nine times higher. As these numbers rise, medical research related to the treatment of HIV, TB and Hepatitis C in correctional settings may become even more common.

Concentration of Selected Subpopulations Behind Bars

Dramatic increases in incarceration, poor and overcrowded prison conditions, and a low standard of health care complicate the ethical questions surrounding research in prisons. Between 1980 and 1994, the number of inmates in federal and state prisons and local jails almost quadrupled — from 501,886 in 1980 to 1,860,520 in 1999.¹ As of 1998, 1 in 150 US residents was living behind bars. The growth rates are quickening at an unprecedented pace: in 1999, the Federal prison population rose by 9.9% (up 10,614 prisoners), the largest 12-month gain ever reported.²

The driving force has been an upsurge in incarcerations for drug-related crimes. Intensified police scrutiny and mandatory minimum sentencing policies have raised the number of adult arrests for drug-related offenses. Between 1985 and 1998 drug arrests nearly doubled, from 718,600 in 1985 to 1,353,300 in 1998.³ Between 1990 and 1996, 72% of the growth in the number of sentenced prisoners was due to increases in arrests for illicit drug-related offenses.⁴

Adding to the concentration of IDUs behind bars are the high rate of recidivism and the revolving cycle of incarceration. The Bureau of Justice,

examining release records for 11 states in 1983, estimated that 62.5% were rearrested for a felony or serious misdemeanor within 3 years, 46.8% were reconvicted, and 41.4% returned to prison or jail.⁵ The cycle of incarceration is particularly significant considering its link with HIV infection: recidivism rates are higher among injection drug users and people with HIV infection. Individuals who are both IDUs and HIV-infected have even higher recidivism rates.⁶⁻⁸

The recent surge in prison and jail populations has concentrated people living with HIV/AIDS behind prison walls - as many as one-fifth of the nation's HIV-infected population pass through prisons and jails.⁹ Nationally, AIDS is the leading cause of death in prison.¹⁰⁻¹²

In response to the surging prison population, the government has constructed new correctional facilities. For the fiscal year 1995, the state and federal governments planned \$5.1 billion in new prison construction.¹³ Nevertheless, overcrowding remains severe.

Historical Perspective on Clinical Trials in Prisons

Historian Jon Harkness opened the conference with a review of the history of clinical trials in correctional settings.¹⁴ During the early 1960s and 1970s, 90% of drugs licensed were first tested in prisoners. Following a series of prison research scandals and widespread concern about the abuse of prisoner research subjects, a committee was formed to review the conduct of these trials and examine whether inmates were capable of giving voluntary and fully informed consent (the 1978 "Belmont Report").

Subsequently, federal regulations limited research in correctional settings to four categories: (1) low-risk studies of "the possible causes, effects, and processes of incarceration, and of criminal behavior"; (2) low-risk studies of "prisons as institutional structures or of prisoners as incarcerated persons"; (3) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more preva-

lent in prisons than elsewhere...); and (4) research that has "the intent and reasonable probability of improving the health or well-being of the subject." Most clinical trials in correctional settings would fall under the last category. Likewise, Office for the Protection from Research Risks (OPRR, now OHRP) guidelines prohibit the implementation of phase I and II trials and studies that would not benefit the inmate as an individual. Phase III studies are generally allowed (where state laws permit clinical research on inmates), when the condition under study is more common among incarcerated populations and the intervention stands to benefit the patient.

Following Dr. Harkness's review, attendees discussed ethical, legal, and medical criteria for the conduct of trials in corrections, considering the existing trials taking place in correctional settings.

Legal and Ethical Conflicts: confine and punish vs. provide care

For health care in prisons, the overwhelming reality is the tension between the conflicting values of medicine and security. The goal of corrections is to confine and to punish. Not surprisingly, security interests often take precedence over prisoners' health. Correctional health services must diagnose, comfort, and treat in a setting designed to deprive and coerce.¹⁵ The biomedical research that takes place in prison must do so within this context; and regulations designed both to protect prisoners from abuse and give them access to innovative therapies must carefully balance this tension between care and punishment.

Regulations and guidelines for the conduct of research in correctional settings

Regulations to protect human subjects (and prisoners in particular) from abuse were issued in 1981 and revised in 1991 by the Department of Health and Human Services and the Office of Protection from Research Risks.¹⁶ The regulations were based on the basic ethical principles for the conduct of human research set forth in the

Belmont Report of 1978.¹⁷ The three main principles- respect for persons, beneficence, and justice- were meant to provide an ethical foundation which could be used to generate specific rules and regulations to govern research in different contexts. However, these principles are difficult to interpret in the correctional setting. Respect for persons, for example, requires that individuals be treated as autonomous agents. Yet the hierarchy in prison makes it extremely difficult for prisoners to act autonomously. Beneficence calls for the best interests of an inmate. Yet what does it mean to look after the best interest of an inmate who is being confined and punished? Justice, again, is difficult to achieve in a setting where the injustices of the larger society are amplified.

Clinical trials guidelines have been in the news this year in the wake of several incidents. As of June, 2000, the NIH required key personnel on clinical research awards to complete training in human subject protection before the NIH will issue an award. Training is available at an online tutorial for NIH intramural investigators, "Protection of Human Research Subjects: Computer-Based Training for Researchers," at <http://helix.nih.gov:8001/ohsr/newcbt>. The Office for Human Research Protections became the organization responsible for safeguarding participants in clinical trials, replacing the Office for Protection from Research Risks (OPRR).

Ongoing clinical trial research in correctional settings

Conference participants learned that inmates do currently participate in clinical trials in a number of correctional institutions. In Texas, for example, the close association between the University of Texas medical programs and corrections enabled inmate participation in a wide range of trials of anti-retroviral agents. In Florida, clinical studies have been carried out at the Central Florida Receiving Facility South Unit under the direction of the University of Miami AIDS Clinical Trials Group (ACTG). In North Carolina, clinical research studies have

also been conducted. These studies, though, are limited to those that have a direct impact on inmate health (e.g., studies of the efficacy of directly observed therapy).

Clinical Trials "Working Groups" and New Guidelines

Conference "working groups" discussed the following topics: who should conduct trials, what type of correctional setting would be appropriate for trials, what type of research should be allowed in correctional settings, and whether coercion and undue influence were factors influencing prisoner participation in research. Each of the four working groups included former inmates, inmate advocates, ethicists, lawyers, correctional representatives, and correctional physicians, as well as audience members. Afterward, a group of 16 experts and 20 observers met to report on issues raised during the working group sessions, and began to formulate more detailed guidelines for the conduct of clinical trials in correctional settings. These guidelines are in preparation; contact the HIV Education Prison Project at Brown University for more information.

In general, conference participants and members of the closed panel appeared to agree that prisoners should have access to clinical trials in correctional settings; however, due to concerns about prisoner vulnerability to coercion and undue influence, the attendees also agreed that the setting for the trial should conform to certain standards and that the conditions at the site should be monitored. Among participants who were in favor of allowing prisoners access to clinical trials, all were in favor of restricting trials to locations where "good clinical practice" was already in place or would be put in place with the clinical trial, so that prisoners would not be restricted to participating in a clinical trial to obtain decent medical care. One interesting proposal called for a national correctional clinical trial review committee (similar to groups that accredit prisons and prison hospitals) that would review each trial proposed for a

correctional setting and monitor the site for compliance with the guidelines' criteria.

Audience participation was welcomed at all points in the proceedings. Discussions were occasionally sidetracked by reports about the dismal state of health care in some correctional settings; however, most participants concurred that "correctional healthcare standards" could not be adequately addressed in this conference. A small group of individuals had warned conference organizers that they would disrupt the proceedings to protest the use of "inmates as guinea pigs." These individuals were effectively silenced by participants who pointed out their lack of familiarity with the linkage between clinical trial participation and improved clinical outcomes^{18,19} and their lack of experience, as clinical providers and/or former inmates, with HIV/AIDS and with the current state of health care correctional settings. Nonetheless, many of the participants who did not oppose clinical trials *per se* sought to monitor more closely the conduct of AIDS clinical trials in correctional settings. Their concerns were reported to groups of ethicists, legal specialists, physicians, and inmate advocates who will be developing the new guidelines.

Overall, participants reported feeling that they were present at a momentous event, because this conference was one of the first national meetings on the topic of clinical trials in correctional settings to be convened in more than 20 years.

Future Directions

Tension is growing between the need to restrict experimental drug trials in prisons and the need to ensure wider access. Despite the need to protect prisoners, the pressures for prevention and treatment generated by the AIDS epidemic are mounting. How can we resolve the need for treatment without sacrificing prisoner protections? The Clinical Trials in Correctional Settings conference explored possibilities for building a consensus among experts. The discussion explored the possibility of establishing a

review process, which could allow prisoner patients access to the benefits of clinical trials without sacrificing current protections. The articles that follow are based on remarks made at the conference.

In order to balance protection from abuse and access to treatment, we must consider several questions: Why are prisoners so vulnerable to abuse? T. Howard Stone addresses the environment of corrections and the conduct of research. How does the current regulatory system protect prisoners from harm and provide them access to benefits? Jeffrey Cohen reviews current OHRP guidelines and their application to the correctional setting. How can legal conditions promote the ethical conduct of research under these new circumstances? Zita Lazzarini addresses the legal context of health care in corrections and how that context affects the conduct of research. Nancy Dubler sets forth the ethical framework for trials in corrections. Finally, Margaret Fischl describes an ACTG trial in the Florida Department of Corrections.

This is an unprecedented historical moment: the time is critical; the issue is vital. We must not back down in the effort to protect prisoners from research abuse. At the same time, we must remain persistent in the effort to provide prisoners with effective HIV treatment and a higher standard of care.

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Coercion and Prisoners as a Vulnerable Class of Human Research Subjects

T. Howard Stone, JD, LLM

The 1.8 million men and women in our nation's prisons and jails remain extremely vulnerable to abuse as subjects for biomedical and behavioral research.¹ Many factors contribute to the peril of research in prisons: a history of exploitation, restrictions inherent on prisoners, and a poor standard of health care. These factors all place prisoners at great risk.

A HISTORY OF ABUSE

Concern for prisoners as a vulnerable class of research subjects is rooted in a history of abuse. The Nuremberg war tribunals exposed the atrocities committed by the Nazis and called to the attention of the world the potential for abuse in research involving human subjects. One result was the Nuremberg code, which established 10 principles of conduct for research on human subjects.²

Yet in the three decades following the Nuremberg trials, widespread abuse and unrestricted medical research on prisoners in the United States continued. It was not until the 1970s when the abuses in prison research began to surface. Jessica Mitford documented the ways in which physicians and drug companies profited from using prisoners as experimental material.³ Numerous federal court cases revealed shocking descriptions of abuse.⁴ A journalist spotlighted the Tuskegee study, which enlisted poor rural black men as subjects for research on the untreated course of syphilis.⁵ While the Tuskegee experiment did not involve prisoners, the scandal spurred an anti-research sentiment in research that uses human subjects.

In recent years public awareness has been heightened. But prisoners still remain vulnerable to abuse in research that takes place outside of the public view. Many factors operate behind bars to place prisoners at risk.

PUBLIC INDIFFERENCE

Cultural indifference to the plight of prisoners exacerbates their vulnerability as research subjects.⁶ Over 74% of persons surveyed in 1998 believe that our courts do not deal "harshly enough" with criminals, while 72.8% of persons polled in another survey believe that there is "too much concern in the courts for the rights of criminals."⁷ Changes in the sentencing structures have resulted in an exponential increase in incarceration rates.⁸ This attitude poses a serious threat to the protection of prisoners' rights; any concern among politicians and the public about the use of prisoners in clinical trials may be remote.

The potential for abuse in research involving prisoners is amplified by the fact that racial minorities are disproportionately represented in our nation's prisons and jails.⁹ A large minority population in the prisons increases the potential for abuse because it contributes to a racist public indifference towards the plight of prisoners. The legacy of the Tuskegee experiments has illustrated the greater potential for abuse of poor racial minorities—the same racial minorities who are disproportionately represented in today's prisons and jails.

CONDITIONS OF INCARCERATION

Concern over the use of prisoners in research not only stems from a history of past abuses and current public indifference, but is also rooted in a number of conditions inherent to incarceration. By nature of their confined environment, every aspect of prisoners' lives is determined by coercion and punishment. Confinement also results in "learned dependency" or "learned helplessness." Guided by entrenched and generally inflexible rules, authorities determine almost every aspect of life in prison, from diet, to exercise re-

gime, access to health care, and recourse to grievance regarding just about any matter. Under these conditions, prisoners' ability to exercise free choice in their decisions to participate in research is severely limited.

Prisoners' vulnerability to abuse is exacerbated by the nature of confinement in a closed environment, isolated from social support. Lack of education and poor literacy skills also contribute significantly to the potential for abuse.¹⁰ Given that clinical investigators often fail to comply with federal regulations that require them to provide subjects with information in language that is understandable to them, prisoners may well not understand informed consent documents.¹¹

Perhaps the most significant factor placing prisoners in a perilous position as research subjects is their poor health status and limited access to quality health care. While prison conditions have greatly improved over the past 30 years, conditions are still deplorable in many institutions and inmates frequently do not receive adequate care. As late as 1989, prison systems in 39 states and the District of Columbia, Puerto Rico, and the Virgin Islands were found to have constitutionally unacceptable conditions, including overcrowding and poor medical care.¹² Even correctional health care providers often do not believe that inmates should receive a community standard of care.¹³ A low standard of health care heightens prisoners' vulnerability because they may decide to participate in clinical trials as a way of obtaining health care that is otherwise unavailable.

UNDUE INFLUENCE

The undeniably poor health care which exists in many prisons seriously impedes the capacity of prisoners to give truly voluntary informed consent

to participate in research. While it may be unlikely that prisoners are routinely coerced into consenting, it is altogether likely that they are unduly influenced. "Coercion" can be defined as a lack of choices that involves a threat, penalty, or the revocation of a right, privilege or benefit. By contrast, "undue influence" refers to a larger category of practices that are not overtly coercive, including bribery, monetary inducements, duress, deceit, or exaggerated misrepresentations of the benefits of research.

In the case of clinical trials for HIV/AIDS, substandard or suboptimal HIV care is likely to act as an undue influence because prisoners may elect to participate in research to obtain care that is not otherwise available. The enticing benefits of a higher standard of care may create a situation in which prisoners are coerced by the conditions of incarceration. Some argue that prisoners, by virtue of their total confinement in such poor conditions, cannot give uncoerced consent and thus should not be used as research subjects under any circumstances.¹⁴

Another likely undue influence in the case of HIV/AIDS research is the "therapeutic fallacy;" that is, the tendency for patients to consent to participation in research at the suggestion of their physician because the patient fails to distinguish between the physician's therapeutic and investigative roles. In prison, where inmates' decisions are so rarely their own, "therapeutic fallacy" is even more likely to be a factor of undue influence. Offenders may have little recourse to alternative care if they do not participate in a research arm of a clinical protocol.

The case for future prisoner participation in human subject research is disquieting. Given historical abuses, poor prison conditions, poor health status of prisoners, and real concerns over the ability of prisoners to provide true voluntary and informed consent, it is essential that we remain vigilant in the effort to protect prisoners from research risks. Professionals in the field, including ethicists, lawyers, and health care providers, must counter public indifference and act as the standard

bearers for prisoners' rights that are implicated by prisoners' participation in human subject research. To ensure that the historical abuse of prisoners is never again repeated, clinical investigators, the institutions they work for, research sponsors, and government officials must implement added protection that is commensurate with prisoners' heightened vulnerability.

Even correctional health care providers often do not believe that inmates should receive a community standard of care.



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Research Infrastructure and IRB/FDA Requirements

Jeffrey Cohen, PhD

As a particularly vulnerable population, prisoners are protected by federal regulations that govern the research of human subjects. A growing public concern over the potential for abuse of human research subjects in the 1970s, prompted the Department of Health and Human Services (DHHS) and the Office for Protection from Research Risks (now called the Office for Human Research Protections, (OHRP) and located in the Office of the Secretary of the DHHS) to issue specific regulations for the conduct of research involving human subjects. In order to implement the protections for prisoners contained in the regulations, we must unravel their complexities. Investigators, lawyers, ethicists, and medical providers must thoroughly comprehend the guidelines in order to follow them closely and ensure that prisoners are provided the necessary safeguards.

STRUCTURE, APPLICABILITY, AND ENFORCEMENT

Part 46 of Title 45 of the Code of Federal Regulations (45CFR46) presents these regulations in four subparts. Subpart A, also known as the "Common Rule," outlines the basic federal requirements for research performed on humans, including requirements for the composition of Institutional Review Boards and general requirements for informed consent. The three other Subparts each apply to research on a specific class of vulnerable human subjects. Subpart B governs research involving pregnant women and fetuses, Subpart C governs research involving prisoners, and Subpart D governs research involving children.

Federal regulations apply only to federally supported or conducted research. For Subpart A, this includes research that is supported or conducted by any of the seventeen federal agencies that have signed on to the Common Rule. Subparts B, C, and D apply only to research supported or conducted directly by the Department of Health and Human Services. The Department of Edu-

cation, which has adopted Subpart D for children, is the only exception. The Human Subjects regulations are enforced through institutional assurances; any institution that conducts federally supported research must have a written assurance of compliance with either the federal agency sponsoring the research or the OHRP before it will be allowed to conduct that research. Any research in a particular institution that is conducted under the auspices of an OHRP-approved assurance must comply with 45CFR46 Subpart C.

Most research that is not federally supported or conducted is under the jurisdiction of the Food and Drug Administration (FDA), which has a different

... risks involved in the research must be "commensurate with risks that would be accepted by nonprisoner volunteers"



Abbreviations Used:

DHHS	Department of Health and Human Services
FDA	Food and Drug Administration
IRB	Institutional Review Board
OHRP	Office for Human Research Protections

legislative authority and a different set of regulations. The FDA and the DHHS regulations are relatively congruent, although there are some differences in the definition of research and in the definition of human subjects. Currently, the FDA does not have a separate set of regulations governing the use of prisoners as research subjects. According to FDA sources, the FDA regards prisoners as a vulnerable population, and encourages researchers to design their research to protect the rights and welfare of this vulnerable population. The FDA also recommends that any IRB exercise extreme care when working with prison populations, paying particular attention to the possibility of coercion, and emphasizing

Web Resources Concerning Clinical Trials in Corrections

HEPP News Website: www.HIVcorrections.org

Adult AIDS Clinical Trials Group (AACTG): <http://aactg.s-3.com/index.htm>

American Foundation for AIDS Research: <http://www.amfar.org/>

Community Programs for Community Research on AIDS (CPCRA): <http://www.cpcra.org/>

National Institute on Allergy and Infectious Diseases (NIAID): <http://www.niaid.nih.gov>

HIV Network for Prevention Trials (HIVNET): <http://www.niaid.nih.gov/daids/hivnet.htm>

AIDS Clinical Trial Information Service: <http://www.actic.org/>

HIVline: The Clinician's Educational Resource: www.HIVline.com

Office for Human Research Protections: <http://ohrp.osophs.dhhs.gov>

The Nuremberg Code: <http://www.niec.net/ipcb/protocols/nurcode/html>

Institutional Review Board (IRB) Guidebook, 1993: Guidance for institutional review boards for aids studies: http://ohrp.osophs.dhhs.gov/irb.irb_guidebooks.htm

Code of federal regulations Title 45, Part 46 Protections for Human Subjects: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

Code of Federal Regulations Title 45, Part 46- Protection of Human Subjects- Department of Health and Human Services (45 CFR 46)

Subpart C- Additional Protections Pertaining to Bio-medical and Behavioral Research Involving Prisoners as Subjects

45 CFR- d46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

45 CFR- d 46.304 Composition of Institutional Review Boards where Prisoners are Involved

- (a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
- (b) At least one member of the board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

45 CFR- d 46.305 Additional duties of the Institutional Review Boards where Prisoners are Involved

- (a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:
 - (1) the research under review represents one of the categories of research permissible under d46.306(a)(2);
 - (2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
 - (3) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
 - (4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.....;
 - (5) the information is presented in language which is understandable to the subject population;
 - (6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in research will have no effect on his or her parole; and
 - (7) where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoner's sentences, and for informing participants of this fact.

45 CFR- d 46.306 Permitted research involving prisoners.

- (a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:
 - (1) the institution responsible for the conduct of the research has certified to the Secretary that the IRB has approved the research under d46.305 of this subpart; and
 - (2) in the judgement of the Secretary the proposed research involves solely the following:
 - (a) study of the possible causes, effects, and processes of incarceration and of criminal behavior.....;
 - (b) study of prisons as institutional structures or of prisoners as incarcerated persons.....;
 - (c) research on conditions particularly affecting prisoners as a classprovided that the study may proceed only after the Secretary has consulted with appropriate experts...and published notice in the Federal Register of the intent to approve such research; or
 - (d) research on practices, both innovative and accepted, which have the intent and reasonable expectation probability of improving the health or well-being of the subject. ...The study may proceed only after the Secretary has consulted with experts and published notice in the Federal Register of his the intent to approve of such research.
- (b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

Existing Guidelines for Research on Human Subjects

Guideline	Source
Nuremberg Code	Nuremberg Military Tribunal decision in <i>United States V Brandt</i> - 1947
Declaration of Helsinki	World Medical Association- 1964, last revised 1996
Belmont Report	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research- 1979
Code of Federal Regulations for the Protection of Human Subjects 45 CFR 46 (with Subpart C pertaining to research involving prisoners)	U.S. Department of Health and Human Services, Office for Protection from Research Risks, National Institute of Health- 1981, last revised in 1991
International Ethical Guidelines for Biomedical Research Involving Human Subjects	Council for International Organizations of Medical Sciences and the World Health Organization- 1982, last revised in 1993

the voluntary nature of the research. The FDA has said that it refers researchers to the DHHS Regulations in Subpart C of 45CFR46 for guidance in conducting research involving prisoners. Researchers and institutions should contact FDA directly for guidance in this area.

SUBPART C: PROTECTIONS FOR PRISONERS AS A VULNERABLE CLASS OF HUMAN SUBJECTS

The explicit purpose of Subpart C (45 CFR 46.301-46.306) is to protect prisoners¹ from abuse when they are used as subjects in research. However, according to the regulations, research involving prisoners should occur only as an exception to the rule. The key sentence in Subpart C states that "except as provided in paragraph A of this section [under very restricted circumstances] biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects." The regulations recognize that prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. The intent of the regulations is thus to provide additional safeguards and protection of prisoners when they are involved in permissible research activities.

The first of these safeguards is a requirement that regulates the composition of Institutional Review Boards (IRBs). At least one member of an IRB that reviews research involving prisoners must be a prisoner or a "prisoner representative" defined only as someone with sufficient or appropriate expertise to fulfill that func-

tion (46.304(b)). The OHRP evaluates the expertise of the prisoner representative on a case-by-case basis when approving the makeup of an IRB. Exclusive of the prison members, all other members of the IRB must have no other association with the prison(s) involved, apart from their IRB membership (46.304(a)).

*The parole board must
not consider participation
as a factor for release.*



The DHHS regulations stipulate that IRBs must ensure several other safeguards before approving research on prisoners. Research conducted or supported by the DHHS must not provide advantages to prisoners that impair their ability to weigh and evaluate the risks and benefits of the research (46.305(a)(2)). Given the institutional context of limited choice, advantages in general living conditions, medical care, quality of food, amenities and opportunity for earnings may result in undue influence on a prisoner's decision to participate. A second requirement is that risks involved in the research be "commensurate with risks that would be accepted by nonprisoner volunteers" (46.305(a)(3)). As noted in the IRB Guidebook, it is critical to understand the regulations' definition of minimal risk. The risks to which prisoners may be exposed by participating in research must be compared with the risks "normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy per-

sons" (46.303(d)) - not the risks normally encountered by prisoners.

Several other minimum requirements must be met for research on prisoners to be acceptable. The procedure for the selection of research subjects must be fair and must not involve "arbitrary intervention by prison authorities or prisoners" (46.305(a)(4)). Information about the research must be presented to the prisoners in language that they understand (46.305(a)(5)). The parole board must not consider participation as a factor for release (46.305(a)(6)). And finally, adequate follow-up care must be provided (46.305(a)(7)).

In addition, the regulations specify that research may be conducted or supported by the DHHS only if it falls into one of the following four categories: (1) research (involving no more than minimal risk or inconvenience) on the possible causes, effects and processes of incarceration and criminal behavior; (2) minimal risk research on prisons as institutions or prisoners as incarcerated persons; (3) research on particular conditions that affect prisoners as a class; and (4) research on practices likely to benefit the prisoner subject (46.306(a)(2)(a) - 46.306(a)(2)(d)).

The category of research on conditions affecting prisoners as a class is particularly relevant to questions of HIV research. Studies under this category could include placebo-controlled vaccine trials, research on certain types of hepatitis, and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults. Like hepatitis, HIV disproportionately affects the prison population.² HIV research in pris-

ons could conceivably be justified on the basis that it affects prisoners as a class, although it remains unclear whether this is actually the case. This research can only be conducted in prisons after the Secretary of DHHS has consulted with experts and published its determination in the Federal Register

The fourth category of permissible research, research on practices that might improve the health or well being of the individual subjects, is also particularly relevant for HIV research in prisons. Because participation in clinical trials is the best way for many HIV patients to access effective treatment, the possibility of therapeutic benefit could allow for prisons to be more accessible to researchers who want to run clinical trials. However the rule is more restrictive than it might seem at first glance. Where such research involves placebo controls, it, too, can only be conducted in prisons after the Secretary of DHHS has consulted with experts and published its determination in the Federal Register. The OHRP will then consult with appropriate experts to evaluate the study. Before

the study may be conducted, DHHS must publish in the Federal Register its intent to go forward with the research. This includes Phase One studies using placebo-control subjects.

CONCLUSION

The federal regulations designed to protect prisoners from abuse are extensive. Unfortunately, the regulations are frequently misunderstood and followed incorrectly. One prerequisite that is commonly overlooked requires the IRB to notify the OHRP of every DHHS-supported study that it approves involving prisoners as subjects. Notification is an indication that the IRB includes prisoner representation, that the research falls under one of the four permissible categories, and that the IRB has ensured all other requirements.

To ensure the protection of prisoners, researchers and other institutional representatives must study the regulations in 45CFR46 and follow them closely.

For additional information see OHRP guidance on its website: <http://ohrp.osophs/dhhs.gov>.

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A Legal Framework for Clinical Trials in Correctional Settings

Zita Lazzarini, JD, MPH

The phrase “legal conditions for research” has a dual meaning. First, legal and regulatory provisions currently set standards for research under certain conditions or may prohibit it in others. Second, statutes, regulations, case law, and policies could be revised and reshaped to promote the ethical conduct of research. Federal regulations issued by the Office for Human Research Protection (OHRP), regulations of the Food and Drug Administration (FDA)[discussed previously in the section on Research Infrastructures by Jeffrey Cohen], case law on constitutional issues, and state laws make up one part of the legal conditions for research. The second aspect, the area in which law could act to ensure ethical conduct of research, is particularly complicated in the age of the HIV/AIDS epidemic. The increasing numbers of HIV-infected prisoners both deserve and demand effective medical care, while rapid advances in development of new pharmaceuticals demonstrate the potential for clinical trials to benefit many persons with HIV, including prisoners.¹ A foundational question, then, is how the law can, in the context of the current legal protections and the HIV/AIDS epidemic, further promote the ethical conduct of research?

From this premise, several basic questions follow. Considering that clinical trials may provide prisoners with access to the therapeutic benefits of innovative treatments, what are the necessary minimal conditions to permit those trials? How can the law create these conditions? What barriers in the law exist to prevent them? This article will review the legal constraints that prevent the promotion of ethical research and then examine specific areas in which the law could help shape the necessary conditions for ethical research.

BARRIERS

There are currently two major barriers to the promotion of ethical trials in prisons. The first is the public perception of prisoners as expendable and undeserving of special treatment [For more information regarding public indifference towards prisoners see Howard Stone’s article in this issue: “Coercion and Prisoners as a Vulnerable Class of Human Research Subjects”]. In this context, it is difficult to advocate for any program or investment that will benefit prisoners. Even efforts to define and enforce a “community standard of care” (for health care in prisons) may flounder because of a general reluctance to provide prisoners with “special care.” This barrier impedes efforts both to protect prisoners from unethical research and to provide them with access to possibly beneficial research.

A second barrier to the promotion of ethical trials is that federal regulations related to research actively discourage research involving prisoners. Aspects of the federal regulations appear vague and contradictory to correctional institutions. The general tone of state and federal regulations is “protectionist” if not actually “prohibitionist.” Under federal regulations, research involving prisoners can only occur as an exception to the rule.² Legal provisions other than the federal regulations also discourage research. At the beginning of the 1990s, laws or regulations banned research involving prisoners altogether in nine states and the federal prison system.³ “Protectionist” regulations have an even wider impact, however. A study from 1995, which surveyed thirty states, found that nineteen specifically banned research in prisons. Two other states had ambiguous policies that may allow for indi-

Abbreviations Used:

FDA	Food and Drug Administration
HIV	human immunodeficiency virus
OHRP	Office for Human Research Protections
PLRA	Prison Litigation Reform Act

vidual participation but effectively exclude prisoner participation because there are no guidelines to encourage it.⁴ Only nine of those states expressly permitted prisoners to participate. Although the current regulatory structure cannot effectively protect prisoners from inadequate living conditions, the regulatory climate does prevent a significant amount of research from taking place.

HOW THE LAW CAN ACT Controlling Prison Conditions

Despite these barriers, there are many areas in which the law could increase prisoner protection and provide legal guidelines that would make ethical trials possible. Perhaps the most significant of these areas is the legal control of prison conditions. The current state of health care and general prison conditions in our nation’s correctional institutions is bleak.⁵ The interests of security and punishment frequently overshadow the interests of medical care, while pressures to reduce costs result in extremely limited medical budgets and a poor standard of care.⁶ [See Howard Stone’s article in this issue: “Coercion and Prisoners as a Vulnerable Class of Human Research Subjects”].

Prison conditions are important to the ethical conduct of research for several reasons. First, poor conditions in prisons have an adverse impact on the process of informed consent. Poor prison conditions (both living conditions and limited access to health care) combined with the extremely coercive

nature of incarceration can create a climate in which the normal benefits of research amount to an undue inducement to participate.⁶ Conditions conducive to truly voluntary consent, then, require establishment and maintenance of a basic level of prison conditions and a community standard for both general and HIV-specific medical care. (See below, Establishing a Community Standard of Care) [See also "An Ethical Analysis of Clinical Trials in Correctional Settings" by Nancy Dubler in this issue.]

Second, poor prison conditions often interfere with the conduct of good research. Security measures, inflexible scheduling, or poor living conditions can adversely affect the quality of the data. If subjects are inaccessible because they are in "lock down" (a common prison procedure which requires inmates to remain in their cells), if they are not allowed access to their medications, or if they are poorly fed, housed, or exposed to additional health risks, the results of the research will be compromised.

The control of prison conditions is a domain in which the law has acted in the past and where the law must act in the future. The United States Supreme Court established the minimum constitutional standard of medical care in prisons in *Estelle v. Gamble* in 1976. The court held that "deliberate indifference to the serious medical needs of inmates constitutes the willful and wanton infliction of pain which the Eighth Amendment is designed to prohibit."⁷ This ruling established a constitutional standard to evaluate the adequacy of medical services. Yet it leaves the term "deliberate indifference" open to a wide range of interpretations and does not require correctional institutions to provide inmates with a community standard of care.

The primary legal recourse for challenging the standard of health care has been case-by-case litigation. Prison litigation has increased dramatically since the 1970s, from 6,600 cases filed by prisoners in 1975 to more than 39,000 in 1994.⁸ Case-by-case litigation has become the primary legal re-

course for monitoring both medical care and prison conditions in general. Numerous cases brought to the courts by inmates resulted in a series of rulings across the country in which the courts ordered judicial control of prison conditions by consent decree. Jails in New York City have been under court supervision since 1978 when the *Benjamin v. Jacobson* case exposed the typically atrocious conditions.⁹ When prisoners sued over conditions at the Oklahoma State Penitentiary in the late 1970s, a judge ordered closure of a section of the prison where conditions were particularly poor.¹⁰ These are just two examples of many cases in which city and state correctional systems have been forced to comply with court intervention.

Despite the inadequate conditions in prisons and jails throughout the country, recent court cases and new legislation seriously threaten advocates' and prisoners' ability to improve those conditions through litigation. In a recent Tenth Circuit Court opinion addressing the issue of prisoners' access to HIV care, one court demonstrated the standards to which prison authorities will be held in decisions regarding inmate health care.¹¹ In *Perkins v. Kansas* an inmate sued the Department of Corrections and the health professionals, claiming that their failure to provide him with combination protease inhibitor therapy for his HIV condition was a violation of his federal constitutional rights under the Eighth Amendment's prohibition of cruel and unusual punishment. The court concluded that the inmate was not entitled to combination therapy under the Eighth Amendment. The court determined that the prison system acknowledged Perkins' HIV disease and had provided him with some care. The court characterized Perkins' demand for protease inhibitor therapy in addition to what he was already receiving as a disagreement over the choice of therapy. After review of this evidence, the court concluded that the prison's actions did not constitute "deliberate indifference" as required for an Eighth Amendment claim. This case suggests that constitutional claims may

not necessarily ensure access to HIV/AIDS care. While the decision in *Perkins v. Kansas* is limited to the Tenth Circuit, the legal precedent is likely to influence other Circuit Courts as well.

Perkins v. Kansas is not the only threat to the legal control of prison conditions. Even more serious is the Prison Litigation Reform Act (PLRA), a new federal law that sets an absolute time limit on how long court action can be effective in controlling prison conditions through consent decrees.¹² Since 1996 when President Clinton signed the act into law, at least twenty jurisdictions have initiated legal battles for control over their prisons; ten have been successful.¹³ The law encourages local officials to bring suits to end court orders. Unless inmates can prove that the current conditions violate constitutional protections against cruel and unusual punishment, judges must suspend court supervision within 90 days.¹⁴ If inmates convince the courts that conditions violate the Eighth Amendment, court supervision continues but correction officials may bring suit again after two years. In addition, the law makes it significantly harder for inmates to file claims against correctional institutions.¹⁵

The PLRA limits the power of federal courts to remedy constitutional and statutory violations in prisons. In a congressional Judiciary Committee meeting, Associate U.S. Attorney General John Schmidt observed that the bill would make it "virtually impossible for states to enter into consent decrees even when the consent decree may well be in the state's best interest for both fiscal and policy reasons."¹⁶ The PLRA strips courts of mechanisms such as population caps, which have traditionally been used to control prison conditions. Meanwhile, states and cities that are regaining control over correctional systems have not adequately improved conditions. In New York, Michigan, Oklahoma, and Tennessee, correctional institutions have successfully ended court supervision despite claims from lawyers and inmate advocates that conditions are still unconstitutionally poor.¹⁶

As a result of the Prison Litigation Reform Act, previous mechanisms used to improve or enforce prison conditions are now unavailable, and thus the improvements made are no longer durable. These setbacks give rise to an urgent need to create additional ways for the law to ensure standards of prison conditions. Despite new restrictions on the ability of federal courts to supervise prison systems, there are several other ways in which the law can, and must act. The law can look outside the courtroom to develop an effective system that can mandate and monitor changes. State legislatures can improve conditions through funding and regulation of prisons and adoption of minimum standards for ethical research in prisons that include adequate prison conditions, monitored by independent authorities. (See below, Independent Oversight of Research)

Establishing a "Community Standard of Care"

The primary area in which the law could be useful is establishment of a community standard of medical care in prisons, particularly HIV care. A community standard of care is important for two reasons. First, prisoners should not experience medical neglect merely because they are incarcerated. Regardless of the holding in *Perkins v. Kansas*, medical care that leads inevitably to treatment failure and death (where an effective means of treatment is available) should not be an acceptable minimum standard of care.

Second, establishing and maintaining a community standard of care would mitigate one source of potential undue inducement for prisoners to participate in clinical trials.

Where prisoner litigants have been denied access to the courts to establish and enforce standards of general and HIV-specific medical care, legal avenues remain. Legislators and regulators could establish the basic requirements for a community standard of care. At the very least, this standard would include:

- Basic medical care and screening on entry;
- Prevention programs for other communicable diseases (TB, STDs);
- Education, counseling and testing for

HIV available to all inmates, and encouraged for inmates with certain risk profiles;

- Systems to identify and continue inmates' pre-incarceration treatment regimens;
- Case management to reduce barriers to adherence;
- Requirements and resources for clinicians to evaluate and change failed regimens (HIV genotyping, resistance testing, and availability of alternative anti-retroviral therapies);
- Programs to plan for continuity of care around prisoner transfer or release from the prison system and to provide bridges to community care.

Considering that clinical trials may provide prisoners with access to the therapeutic benefits of innovative treatments, what are the necessary minimal conditions to permit those trials?



INDEPENDENT OVERSIGHT OF PRISON RESEARCH

Another area in which the law can ensure the legal conditions for the ethical promotion of research is improved oversight of prison conditions and proposed research in prisons. Neither OHRP nor institutional review boards, the two bodies invested with responsibility for protecting subjects, are well-situated to undertake this review. For example, ensuring that the standard of care inside prisons is high enough to avoid improper incentives for prisoners to participate in clinical trials will require intensive and rigorous monitoring. An oversight body must supervise not only prison conditions, but also changing scientific standards, and the integration of those evolving standards into the procedural norms of prisons. The existing oversight in many institutions would be inadequate to do this. If the current sys-

tem, which has been largely dependent on consent decree-authorized monitoring, disappears, independent oversight will be even more essential.

As specified by OHRP and FDA regulations, institutional review boards approving research that involves prisoners must include a prisoner representative, and must certify to the OHRP that all of the required conditions for using prisoners as research subjects have been met.¹⁷ However, IRBs cannot easily assess many of the conditions necessary for ethical research in prisons. IRBs are overloaded and facing tremendous pressure to review studies that are done outside of prisons. The level of scrutiny that is needed to review the special conditions related to using prisoners may be beyond the capacity of IRBs as they are currently structured. For example, in order for an IRB to carefully review the possibility of undue influence and other issues that may hinder the informed consent process, someone must carefully evaluate a wide range of prison conditions, as well as the special deficits particular to the prison population. Other constraints may limit the ability of IRBs to provide the necessary supervision.

A recent study by the Office of the Inspector General of the U.S. Department of Health and Human Services provides additional cause for concern. A series of four reports focused on review mechanisms, review oversight, and monitoring of human subjects.¹⁸ The findings suggest that current research review mechanisms, mandated by federal regulation, are inadequate. The study also suggests researchers themselves are often unaware of the ethical principles and regulations that apply to their research.¹⁸

CONCLUSION

Although law certainly has a vibrant role to play in establishing and monitoring conditions necessary for the ethical conduct of research in prisons, essential questions remain. If there is a consensus that clinical trials can benefit prisoners, how can the necessary and feasible conditions to permit research be established? Is this best accomplished by convening panels of experts, through federal guidance, state law or policy-making, or through independent boards

outside of the IRB process? How will compliance with these standards be monitored- through IRBs, independent monitoring boards, or through the use of the court system and consent decrees? In order to create the legal conditions and a correctional atmosphere that is truly conducive to clinical trials in prisons, we must resolve these questions.

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An Ethical Analysis of Clinical Trials for AIDS Drugs in Correctional Settings

Nancy Neveloff Dubler, LLB

Research with human subjects is always ethically problematic. It subordinates the interests of the patient to the need for knowledge. It places a barrier between the doctor and the patient; rather than do what the physician thinks is best for the patient, the physician must proceed as the protocol commands and administer the treatment that the randomization dictates. Yet our society, like other modern legal and ethical systems, has decided that the benefits of research - enhanced knowledge and greater ability to combat disease - justify maneuvering on the edges of morally acceptable behavior.

Within medical research the randomized, double blinded clinical trial is the gold standard for determining the safety and efficacy of treatment regimens. Because of the moral difficulties with any research enterprise, there is shared agreement that this methodology is only permissible when there is a genuine question to be answered. Benjamin Freedman notes that by requiring an investigator to have "no treatment preference" throughout the course of the trial, the ethical condition of equipoise presents insuperable obstacles to the ethical conduct of controlled trials. He resolves this conflict by suggesting an alternative definition of "clinical equipoise," in which the requirement is satisfied if there is genuine uncertainty within the expert medical community - not necessarily in the mind of the investigator - about the preferred treatment.¹ While this understanding of equipoise does allow for the ethical conduct of clinical trials, it does not change the inherently problematic nature of research on human subjects. The potential for ethical compromise remains critical.

If all research raises ethical issues, research in correctional settings com-

pounds the dilemmas. Prisons and jails are places of systematic deprivation. Privacy is unknown; power may be, and often is, exercised by correction officers and administrators in arbitrary and abusive ways; the justice system, having executed its sentence, rarely interferes in the daily dramatic and brutal encounters among persons on both sides of the bars.

Medical care in correctional settings, the framework for clinical research, raises a different and equally important set of issues. In 1976, the United States Supreme Court held that "deliberate indifference to the serious medical needs of inmates constitutes the willful and wanton infliction of pain which the Eighth Amendment is designed to prohibit" (*Estelle v. Gamble*, 1976).² This judicial holding that the constitutional barrier to "cruel and unusual punishment" mandates the provision of medical care, provided the foundation for the establishment and improvement of health services in the nation's jails and prisons. Yet the constitutional adequacy of these services is regularly contested in federal courts as inmates strive for decent care and institutions struggle to provide efficient and cost-containing services. Many prison and jail health services are inadequate or just barely able to fend off constitutional attack.

If our post-Nuremberg³ society agrees on any ethical norm, it is the idea that only the uncoerced, informed and voluntary consent of a decisionally capable potential subject permits the inclusion of that person in research. That subject should then have the right to refuse participation at the outset and at any time during the trial. Finally, the participation of the subject, and the specific data about care, should be confidential. But all of these elements are

Abbreviations Used:

DSHEA	Dietary Supplement and Health Education Act
FDA	Food and Drug Administration

goals and not givens in a prison setting.

Prison is the ultimate "total institution."⁴ Inmates are not free to make decisions that would structure their lives and change the character of time, space and vocation. Exercises of free will and discretion to edit and amend one's lifestyle are largely precluded in a prison setting. Consequently, it was assumed that research in prisons was generally unacceptable because of the conditions themselves and because these conditions made it impossible for inmates to provide legally and ethically adequate informed consent.

When the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was engaged in the enterprise of drafting federal regulations governing research on human subjects, it assumed that correctional settings were, by and large, inimical to research ethics. For this reason the federal regulations are drafted to preclude research unless it is "a study of the possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects; [or a] study of prisons as institutional structures or of prisoners as incarcerated persons. . . [or] research on conditions particularly affecting prisoners as a class. . . [or] research on practices, both innovative and accepted, which have the intent and reasonable probability of improving health or well-being of the subject."⁵

These conclusions were not only based on the analysis of limitations of

individual freedoms; they grew out of the history of abuses that medical research had wrought in prisons settings. The most dramatic were those so-called "experiments" in the concentration camps of Nazi Germany. In fact, these procedures were merely systems for administering pain, suffering and torture. But there was also a history of research in United States' prisons that left scholars, regulators and medical experts uneasy about and wary of continued research in coercive settings.⁶

There was, at the time of the drafting of the Federal regulations, one set of voices that questioned the wisdom of precluding research in prison settings. When members of the National Commission held hearings at Jackson State Prison in Michigan in November of 1975, a leader of the inmates stated at the hearing: "Ladies and gentlemen: You are in a place where death at random is a way of life. We have noticed that the only place in this prison that people don't die is the re-

search unit. Just what is it that you think you are protecting us from?"⁷

But the moral consensus held, and from the enactment of the Federal Regulations until the early 1980s there was little or no research in the nation's prisons and jails. In the mid-1980s the explosion of the AIDS epidemic changed the dynamic of the discussion and escalated the demands of prisoners for access to research rather than protection from research.

An inmate: "We have noticed that the only place in this prison that people don't die is the research unit."



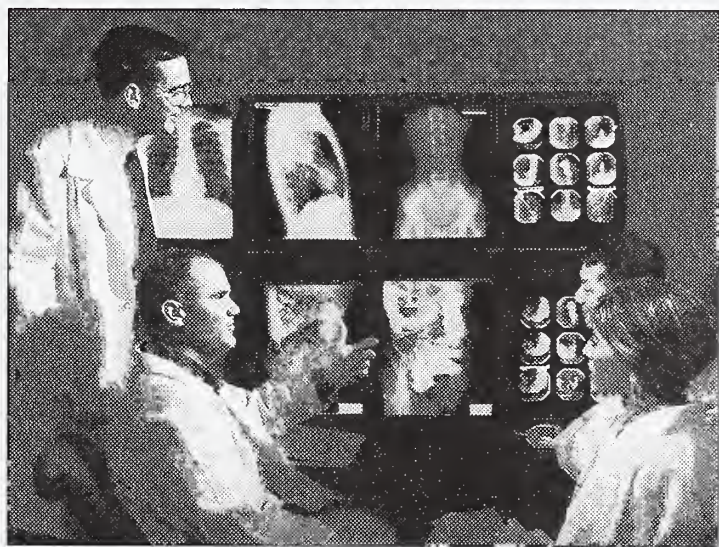
At the start of AIDS treatment and certainly at the beginning of effective treatment so little was known about the

disease, its mechanisms of replication and effective means of treatment, that virtually all treatment was delivered under the design of research protocols. Given that one of the most efficient means of transmission was the sharing of needles used by IV drug users and given the state and federal wars on drugs many drug users were also prison inmates. To exclude inmates was to exclude the single greatest class of HIV-infected persons.

In response to this situation and with the cooperation of the New York City Department of Health and the Prisoners' Rights Project of the New York City Legal Aid Society, Dr. Victor W. Sidel and I convened a working group to consider the ethical and practical issues that might alter the previous analysis and supply the foundation for a revised understanding of the ethical and regulatory permissibility of some research in prisons.

The working group considered whether prisons, as inherently coercive settings, could ever foster the quality

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of independent individual consideration that is the prerequisite for ethically justified research. It deconstructed the notion of informed consent to see whether and under what conditions prisoners might be able to provide ethically justified choice. Finally it examined the language of the federal regulations to see whether, drafted as they currently are, they might support research on AIDS in a locked setting. The working group concluded that prisoners can in fact be as fully capable of making the decision of whether or not to enroll in an AIDS treatment trial as non-prisoners.⁸ Given the high mortality of the disease and the fact that experimental drugs have proved to be efficacious, if prisoners are denied the right to participate in drug trials for AIDS, they are being denied opportunities for benefit that are available to those outside of correctional settings. Here, considerations of justice and respect for persons (as per the National Commission's recommendations) might demand opportunities for inmate participation rather than their exclusion. Because these trials are potentially beneficial as well as potentially harmful, denying prisoners the opportunity to participate would be to punish them beyond the declared sentence and may be challenged as a new sort of cruel and unusual punishment. Therefore, Sidel and I conclude that inmates "need to be *protected* from research designs that can acquire data through other routes and may present risks to inmates as a class. [However], inmates need to be *provided with access* to clinical trials of new and innovative therapies that present the possibility of direct benefit to the subjects."⁸ The resulting publication of the working group's conclusions and reasoning was crucial to changing state and federal systems' responses to the challenges of AIDS.

But the times are now different. We have not won the war against HIV, but we have breached the fortress and bested the enemy in a few skirmishes. The ethical analysis must be updated to meet the present conditions. In the mid 1980s the only treatment available was within research protocols. Since

that is not the case today, our analysis of what is ethically acceptable must be re-examined to meet the present state of diagnosis and treatment.

There are now standard protocols for multiple drug therapies that, while perhaps not eradicating the virus, do keep it at bay for many infected persons. These must be made available to inmates as the standard of care. And, even more daunting for correctional systems, they must be able to provide the nutritional support and the schedule of meals and medications that permit the inmate maximal benefit from the regimen; this may require modifying some of the basic institutional rules and regulations. To do anything less would be, in my judgment, a violation of the constitutional standard and the ethical norm. Since treatment exists for a life-threatening disease it must be available to inmates - not to do so would surely indicate "deliberate indifference." Once it is available, so that an inmate has the choice between treatment in the clinic and treatment within a protocol, then the option to join a research program can be ethically justified.

The question, of course, is how one judges the adequacy of the services provided and who should be charged with the responsibility for making this finding. I would argue that this is a matter left to the research team. They are the experts and we should expect them to review the care provided, engage in a randomized review of case records, examine the treatment plans and reach a conclusion as to whether the care is acceptable according to commonly understood standards of care. If they can certify that the protocols and procedures for administering HIV care are acceptable then they should be permitted to present their protocols to inmates as one more choice.

This is a high hurdle to vault. Many prison and jail health services will not pass this test. In these facilities research would not be ethically permissible. The fact that this places a new burden on researchers should not deter us from insisting on the process described. Treatment is ethically and

legally mandated; research is always optional. The opportunity to enroll inmates in research depends upon the availability of a real choice that makes informed consent possible in these dark and deprived settings.

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Clinical Trials Within the Florida Department of Corrections

Margaret Fischl, MD

This overview presents the issues and mechanics involved in implementing clinical trials within the Florida Department of Corrections.

The relationship between the University of Miami and the Florida Department of Corrections (DOC) first began in 1996 when the prohibition of clinical trials in prisons was lifted. The two institutions joined forces to formulate a program that would provide inmates with access to anti-retroviral research studies. The program was designed so that all aspects of the treatment would provide clinical benefits to the participants. To ensure that quality research would be conducted, we used an integrated approach within the DOC that would allow for proper screening, enrollment, and follow-up care for the participating inmates. We also guaranteed the safety of these inmates at all times. The University's close interactions with the DOC allowed them to provide consultation and supplemental educational services on HIV therapies and interventions.

ADMINISTRATIVE STRUCTURE

With Dr. Fischl as the principal investigator, the clinical trials are both funded and administered by the auspices of the University of Miami. The DOC facilities are regarded as an off-campus, or ancillary, site within the primary site at the University. All clinical trials research taking place in prison is subject to the full regulatory requirements of the University of Miami and its IRB. To provide additional protections, there is a cooperative agreement with the Central Florida Reception Center to work towards meeting federal regulations from OHRP, as well as compliance with the FDA.

Patients are followed and managed by the University of Miami's staff, but remain within the DOC. University research staff are charged with keeping the DOC medical records, as well as writing orders and consultations. University staff also work with the medical staff at vari-

ous DOC institutions to facilitate the research process.

INMATE PARTICIPATION

Inmates gain access to the trials through self-referral or through referrals from the DOC staff. At first contact, research staff will discuss HIV status and clinical details (such as CD4 count and viral load) with the participants. The researchers will then explain to each individual all the treatment options that are within the current treatment guidelines. If the inmate wishes to be treated for HIV infection at this point, the staff will present treatment options within the DOC, including the option to participate in a clinical trial. The inmate is given the choice of whether or not to be treated within a research study, and if so, which study.

*... the clinical trials are
both funded and
administered by the
auspices of the University
of Miami.*



Consent is constantly reviewed as participants and researchers go through the various steps of the research process. Researchers ask questions to ensure that participants fully understand what is expected, what is required, and what rights they have. Like any other subjects, inmates are active participants in the trials. They become familiar with the drug(s), and receive dispensing instructions and a dosing schedule. Inmates are also active participants in the management of their own side effects. All inmates participating in the study are asked to make a commitment to long-term follow-up, regardless of their period of incarceration. To facilitate follow-up once the inmate has left the correctional system, the re-

Abbreviations Used:

AIDS	acquired immunodeficiency syndrome
OHRP	Office of Human Research Protections
DOC	Department of Corrections
IRB	institutional review board

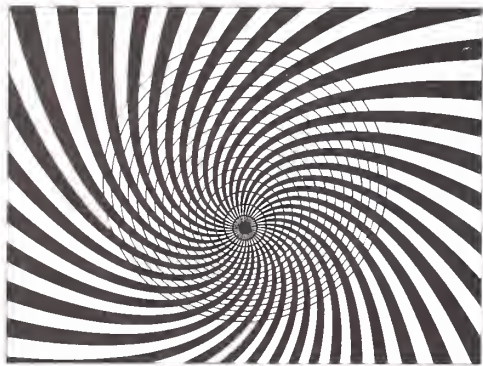
search team sets up a plan with inmates for the time after their sentence is over.

Collaboration between the Florida Department of Corrections and the University of Miami is ongoing and evolving. Inmates have shown increasing interest in the clinical trials that are currently approved. They have also expressed interest in other trials, which they consider critically important, but which are not yet available to them because of Federal Regulations. The experience of clinical trials in the Florida Department of Corrections suggests that expanding prisoners' access to trials would help guarantee the provision of a high standard of medical care as well as keep pace with the changing treatment opportunities in HIV.

Margaret Fischl, MD, Director of the AIDS Clinical Research Unit HIV/AIDS Program at the University of Miami, and chair of the pivotal trial that approved the use of Zidovudine, has been involved in HIV research since May of 1982. Her relatively recent involvement in clinical research within the prison system was spurred by queries from prisoners and their families, and by a desire to improve the health care for inmates with HIV infection.

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IMAGES IN MEDICINE

∞ Gangrenous Cholecystitis ∞

Ulises Torres, MD, and Peter Baute, MD, FACS

A 71-year-old hypertensive diabetic male presented in the emergency department with severe epigastric pain of rapid onset, accompanied by nausea and emesis. Physical examination showed marked epigastric and right upper quadrant tenderness, guarding, and rebound. Computerized Axial Tomography demonstrated pericholecystic fluid, high attenuation bile (figure A), gas in the lumen of the gallbladder and in the gallbladder wall, and distension of the gallbladder (Figure B). At open cholecystectomy, a tensely distended blackish, green gangrenous gallbladder was removed. Cultures of the gallbladder bile showed *C. perfringens*, *Gamma streptococcus*, *Lactobacillus sp*, and coagulase negative *Staphylococcus*. Patient was treated with ciprofloxacin, ampicillin/sulbactam, metronidazole. Six days after the operation the patient was discharged in stable condition.

Ulises Torres, MD, is a general practitioner completing an externship in surgery at Kent County Memorial Hospital.

Peter Baute, MD, FACS, is an attending physician in the Department of Surgery at Kent County Hospital.

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Figure A.

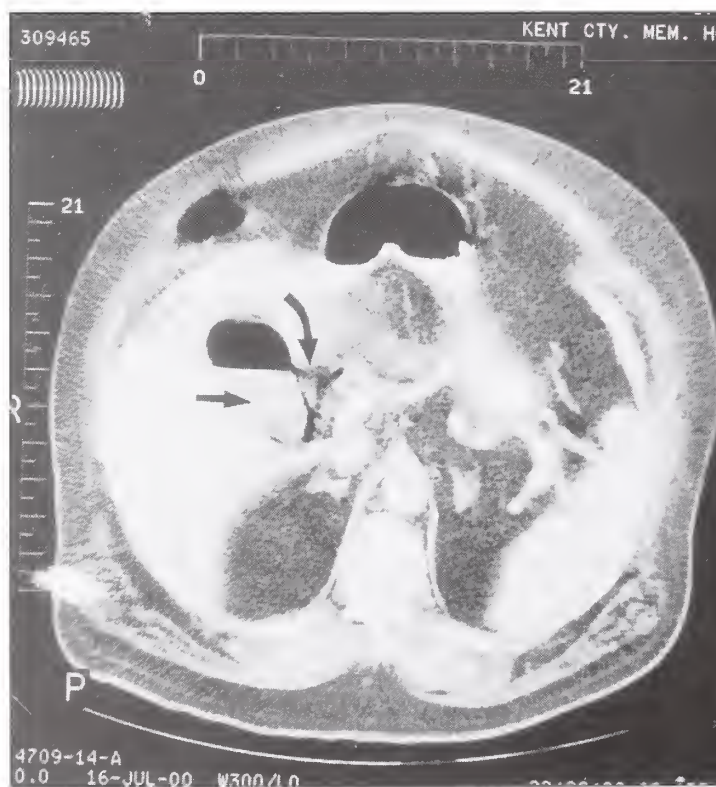
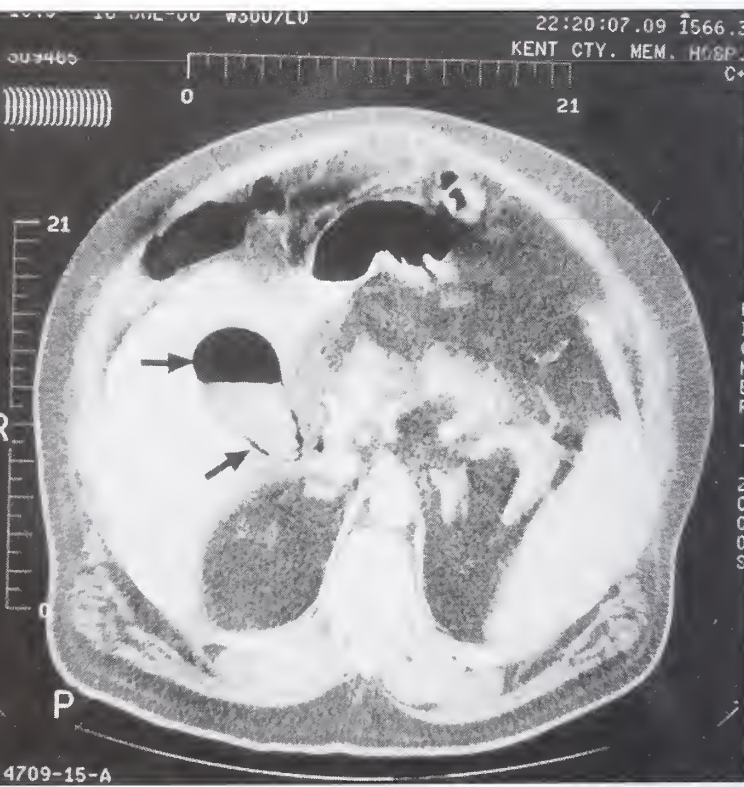
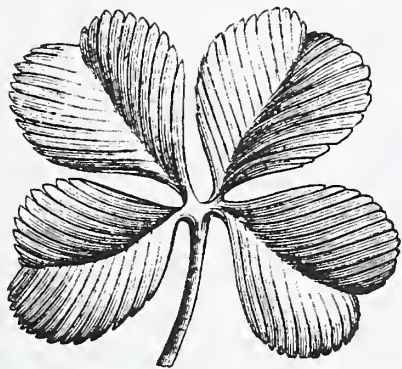


Figure B.





Medical Myths

Ignorance is preferable to error; and he is less removed from the truth who believes nothing, than he who believes what is wrong. — THOMAS JEFFERSON, Notes on the State of Virginia



Patching the Eye Improves Comfort and Healing in Patients with Corneal Abrasions

Elliot M. Perlman, MD

The traditional management for corneal abrasions is to patch the eye firmly for at least 24 hours. Several recent studies, however, have shown that patching provides no benefit in terms of healing time or comfort.¹⁻³ One of these reports² was a large randomized controlled prospective study (201 patients) that compared 24-hour patching to non-patching for simple traumatic abrasions and abrasions due to small foreign bodies. The study design assured that the patches were placed properly. The size of the healing abrasions was measured and the patients were asked to grade their symptoms on a numerical scale. Although the nature of the study did not allow it to be a masked study, it did conform well to a good evidence-based medicine evaluation. The patients who had no eye patch had less pain, less "blurry" vision and had faster healing than the patched group. (It should be noted that—for large abrasions—over 10 mm²—the patched eye had a tendency to heal more quickly.)

In addition to its lack of efficacy, patching itself may not be a benign intervention for several reasons:

- 1) Patching eliminates binocular vision.
- 2) Patching might be more uncomfortable for the patient, especially in hot humid weather.
- 3) If a potential pathogenic bacterial inoculum is present from the injury, patching might create a warm, moist environment to enhance bacterial growth.
- 4) Patching precludes the use of simultaneous ocular medications, such as topical antibiotics.
- 5) Patching may decrease the oxygen supply to the corneal epithelium, forcing it to utilize anaerobic metabolism.

Despite evidence to the contrary, patching is still often recommended^{4,5} as the standard of care. Why is this so?

Medical myths persist for many reasons. In the case of abrasions, the physician sees a patient in obvious pain. Rather than say "there's nothing I can do," the physician would prefer to "do something."

More importantly, most myths make some pathophysiologic sense. Corneal abrasions are so painful because there is a very high density of sensory nerve endings in the corneal epithelium (only rivaled by the number of nerve endings in the anal mucosa). We presume that, when the patient blinks, the eyelid impinges on these exposed nerve endings and the patient experiences pain. Moreover, this frequent eyelid motion could mechanically wipe off the epithelial cells sliding in to fill the defect. It seems logical, then, that firm patching would stop this eyelid movement. As I've noted above,

these factors that seem to favor patching are not supported by current studies.

The second pathophysiologic rationale for patching is that some form of eyelid closure is often required to heal pathological epithelial defects. The corneal epithelium is unusual in that it requires good sensory innervation to maintain itself. For example, if the first division of the trigeminal nerve is severed, corneal sensation is lost. In this situation, spontaneous epithelial defects (identical in appearance to traumatic corneal abrasions) can occur. The resulting condition—termed neurotrophic keratitis—is very difficult to manage. It often responds only to tarsorrhaphy, a minor surgical procedure in which the eyelids are sutured together. In effect, tarsorrhaphy is equivalent to "very long term" patching. Presumably the treatment of pathological epithelial defects may have become extrapolated to the management of abrasions in normal corneas.

SUMMARY:

In managing small simple corneal abrasions, patching is not necessary and is not really indicated. Antibiotic drops and systemic analgesics are appropriate for these abrasions.

For very large abrasions, patching may speed healing.

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Community Acquired Pneumonia and Treatment Priorities

Liudvikas Jagminas, MD, FACEP

In 1999, the Health Care Financing Administration (HCFA) asked each Peer Review Organization (PRO) in the country to focus quality improvement initiatives on eight specific areas, pneumonia being one of them. HCFA developed a national set of quality indicators based on published guidelines. These indicators principally focus on treatments and interventions that can decrease patient morbidity and mortality. The major focus in the pneumonia quality improvement initiative was antibiotic administration within 8 hours of hospital arrival, appropriate antibiotic selection, and blood cultures prior to antibiotic administration.

Pneumonia, historically known as the "old man's friend," is estimated to afflict approximately 4 million people annually in the United States, resulting in approximately 600,000 hospitalizations, 78,000 deaths, and 64 million days of restricted activity.^{1,2} The economic impact of the disease is enormous, with an estimated annual expenditure of \$4 billion for the care of community acquired pneumonia (CAP) patients.³ From a health economics perspective it is important to be aware of the costs associated with inpatient therapy which are approximately 20-fold higher than those associated with outpatient care.² Of the patients with CAP, approximately 80% may be treated as outpatients, whereas the remaining 20% require ad-

Abbreviations Used:

CAP	community acquired pneumonia
HCFA	Health Care Financing Administration
IDSA	Infectious Diseases Society of America
PORT	Patient Outcomes Research Team
PRO	Peer Review Organization

Figure 1

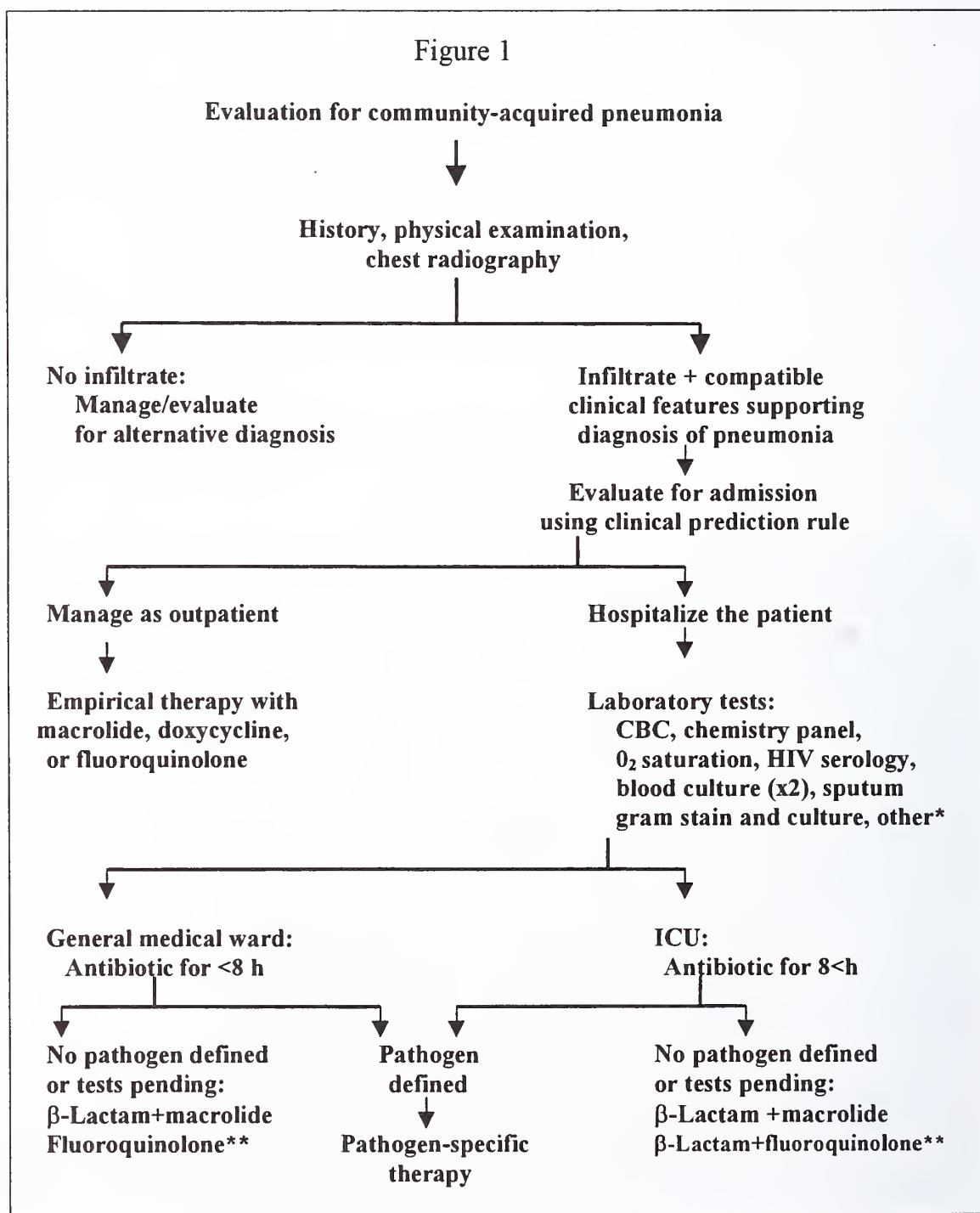
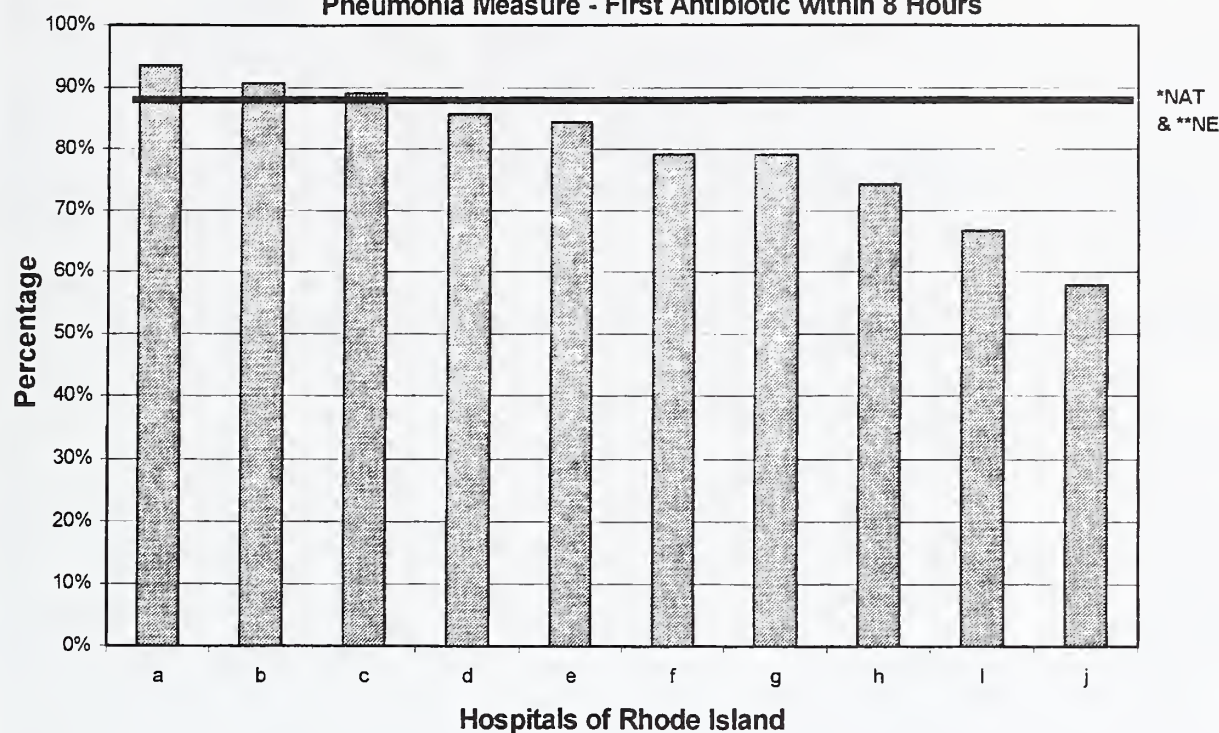


Figure 2

Pneumonia Measure - First Antibiotic within 8 Hours



Based on Fee-For-Service Medicare Beneficiaries Discharged from July 1998 - December 1998

*NAT = Rate of National Top Ten States

**NE = New England Average Excluding Rhode Island

mission to hospital for initial therapy. The mortality rates in these two groups of patients differ significantly, with figures of less than 1% and 20% respectively⁴ and as high as 50% for patients requiring admission to an intensive care unit.^{5,6}

With respect to etiology, the single most important pathogen, particularly in patients who are seriously ill, is *Streptococcus pneumoniae*. A meta-analysis of studies spanning 30 years showed that of 7,000 patients in whom a causative agent was found, *S. pneumoniae* was identified in 66%. It was also responsible for two thirds of the deaths from pneumonia.⁴

For outpatients, causative agents include the atypical organisms such as *Mycoplasma pneumoniae* and *Chlamydia pneumoniae*, plus *S. pneumoniae* and *H. influenzae*. Of these, *Mycoplasma* is the most common agent.^{7,8,9} As one progresses from outpatients to those ill enough to require hospital admission and those who acquired their infection in nursing homes, one sees that the pneumococci are important throughout but that gram-negative rods become important as well.^{10,11,12} Although these pathogens certainly do not occur with the same frequency as *S. pneumoniae* or *M. pneumoniae*, the overall mortality associated with gram-negative rods is substantial and is of the order of 33%.¹³

Despite the desire to tailor treatment to the specific pathogen in each case, timely, definitive determination of the etiologic agents is seldom achieved. Clinical criteria do not provide definitive etiologies¹⁴ and chest radiographs, although useful to diagnose pneumonia, rarely provide a specific etiology.¹⁵ Even when extensive diagnostic testing is employed, an unambiguous etiologic diagnosis is obtained in only about 50% of cases,¹⁶ and a diagnosis is often not available for hours or days. Given the evidence of improved

outcome with the earliest possible intervention^{5,17} and the likelihood of inconclusive diagnoses even with extensive (and costly) testing, guidelines are needed to suggest appropriate initial empiric treatment of CAP in the absence of a clinically confirmed etiology.

THE FOLLOWING IS AN EMPIRICAL SELECTION OF ANTIMICROBIAL AGENTS FOR TREATING PATIENTS WITH CAP:¹⁸

* Outpatients:

Generally preferred (not in any particular order):

doxycycline, a macrolide, or a fluoroquinolone. Selection should be influenced by regional antibiotic susceptibility patterns for *S. pneumoniae* and the presence of other risk factors for drug-resistant *S. pneumoniae*. Penicillin-resistant pneumococci may be resistant to macrolides and/or doxycycline. For older patients or those with underlying disease, a fluoroquinolone may be a preferred choice; some authorities prefer to reserve fluoroquinolones for such patients.

* Hospitalized patients:

General medical ward

Generally preferred: an extended spectrum cephalosporin combined with a macrolide or a beta-lactam / beta-lactamase inhibitor combined with a macrolide or a fluoroquinolone (alone).

Intensive care unit

Generally preferred: an extended-spectrum cephalosporin or beta-lactam / beta-lactamase inhibitor plus either fluoroquinolone or macrolide.

Alternatives or modifying factors:

Structural lung disease: antipseudomonal agents (piperacillin, piperacillin-tazobactam, carbapenem, or cefepime) plus a fluoroquinolone (including high-dose ciprofloxacin).

Beta-lactam allergy: fluoroquinolone ± clindamycin.

Suspected aspiration: fluoroquinolone with or without clindamycin, metronidazole, or a beta-lactam/beta-lactamase inhibitor.

The IDSA support the clinical prediction rule devel-

oped by the Pneumonia Patient Outcomes Research Team (PORT) for making decisions regarding hospitalization.¹⁹ This rule stratifies patients into five risk categories based on their medical history and presenting signs and symptoms. Those in the lowest risk categories, generally younger patients without comorbid conditions and no or minor derangements in their vital signs, can be safely treated as outpatients.

Prompt antimicrobial treatment should be initiated expeditiously once the diagnosis of pneumonia is established with chest radiography. If the patient is able to produce sputum, a sample should be sent for Gram stain in order to facilitate antimicrobial selection. For patients requiring hospitalization for acute pneumonia, it is important to initiate therapy in a timely fashion. In an analysis by Meehan et al. of 14,000 patients they showed that administration of antibiotics within 8 hours of hospital admission was associated with a decrease in 30 day mortality.²⁰ (odds ratio [OR], 0.85; 95% CI, 0.75-0.96) This is one of the few studies to look at a large group of patients and outcomes related to the timing of antibiotic administration. Therefore, antibiotic treatment should not be withheld from acutely ill patients because of delays in obtaining appropriate specimens or the results of Gram stains and cultures, especially in light of the fact that an etiologic agent can only be identified in up to 50% of CAP cases. In addition, time to antibiotic administration is an established (recognized) quality indicator and will be reported and remeasured (refer to Rhode Island data

in Figure 2 showing the ranking of RI nationally and within New England on time to antibiotics. This will be part of public reporting in the state.

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Employee Participation in Employer-Sponsored Health Coverage, Rhode Island, 1999

Jay S. Buechner, PhD

Employer-sponsored group health insurance is the means by which most working-age Americans and their dependents obtain health care coverage. In Rhode Island, a recent survey of employers with three or more employees showed that 79% of these employers offered group health coverage to some or all of their employees.¹ Because larger firms were more likely to offer coverage, 94% of all employees worked in firms where coverage was offered.²

However, even where employers offer coverage, there are many reasons why employees and their dependents may not be enrolled in their employers' health plans. The most common ones are:

- Some employees are not eligible to participate in their employers' plans, usually because they work less than full-time or were hired recently.
- Some employees who are eligible choose not to enroll in their employers' plans, usually because they have coverage through an alternate source or do not want to pay the employee share of the premium.
- Some employees with families are enrolled in individual (employee-only) plans, either because their employers do not offer family coverage, their dependents have coverage through an alternate source, or they do not want to pay the additional employee premium share for family coverage.

This analysis presents data on employee participation in employers' health benefit offerings from a recent survey of Rhode Island employers.

Methods

Between September 1999 and January 2000, 1,486 Rhode Island employers provided information regarding the health benefits they offer their employees and their employees' participation in these of-

ferings. The survey was a self-administered mail-out/mail-back questionnaire and requested information on benefits as of June 30, 1999. The sample included firms with three or more employees at Rhode Island locations and was structured to allow comparisons between public-sector and private-sector employers and among employers grouped by number of

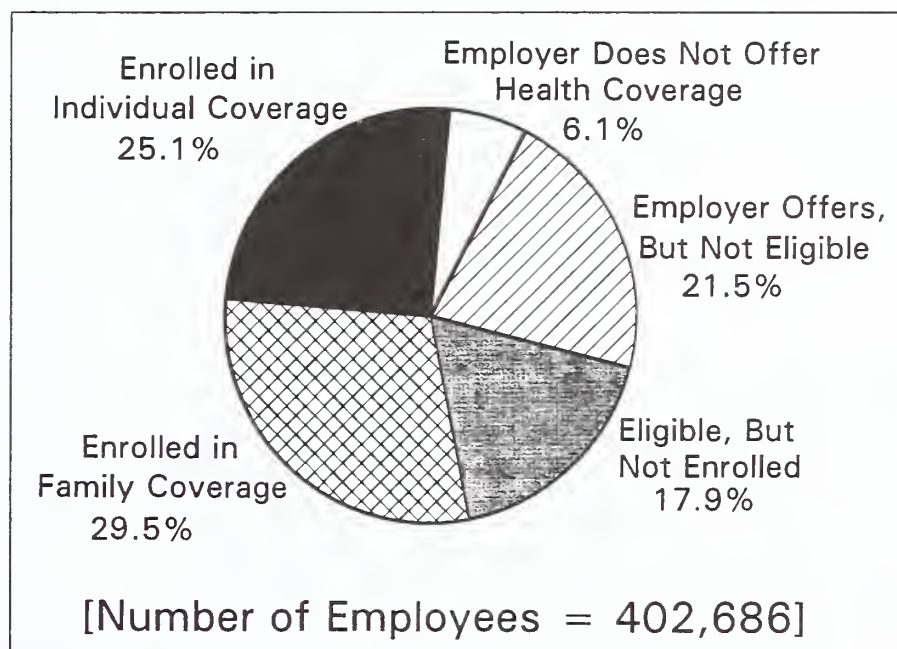


Figure 1. Health Insurance Status of Employees, Rhode Island, 1999.

Table 1.
Health Insurance Status of Employees,
by Full-Time / Part-Time Employment, Rhode Island, 1999

Health Insurance Status of Employees	Full-Time Employees	Part-Time Employees	All Employees
Employer does not offer coverage	3.6%	12.9%	6.1%
Employer offers coverage, but employee is not eligible	8.1%	58.8%	21.5%
Employee is eligible but not enrolled	17.8%	18.2%	17.9%
Employee is enrolled in individual coverage	32.3%	5.1%	25.1%
Employee is enrolled in family coverage	38.3%	5.0%	29.5%
Number of employees	296,042	106,644	402,686

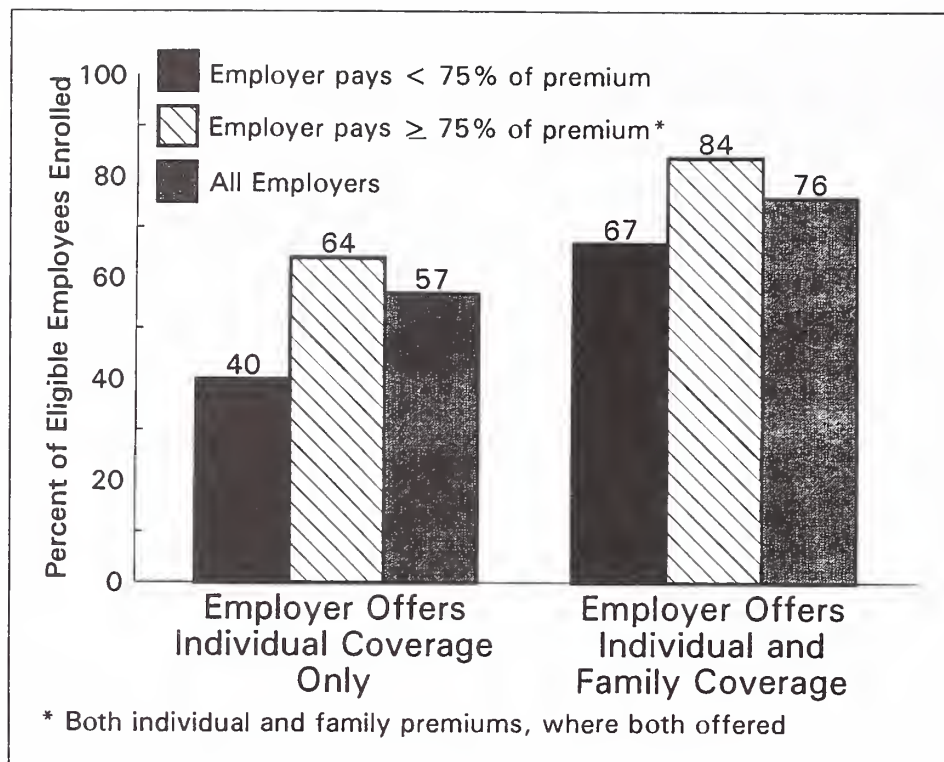


Figure 2. Enrollment in Employer-Sponsored Health Coverage, by Employer's Contribution to Premium, Rhode Island, 1999.

employees (3-9, 10-24, 25-49, 50-99, and 100 or more, with between 272 and 302 respondents per group). Firms received up to three mailings to solicit their participation in the survey; the final mailing was accompanied by a telephone contact attempt. 51% of sampled firms responded.

Results

In all firms responding to the survey, including both those who offered coverage and those who did not, only 55% of employees were enrolled in employer-sponsored health plans. (Figure 1) The largest group of unenrolled workers was the group of employees who worked in firms that offered coverage but who were not eligible to enroll (22%). Nearly as large was the group of workers who were eligible but chose not to enroll (18%). Only 6% of employees worked in firms where coverage was not offered to any workers.

The situation among part-time workers was substantially different from that among other workers. Only 10% of all part-time workers were enrolled in employer-sponsored health plans, and nearly three in five (59%) were not eligible for the benefits their employers provided to other workers. (Table 1) More part-time workers (13%, vs. 4% of full-time) were employed in firms that did not offer coverage, and even among the minority of part-time workers who were eligible to participate, nearly two-thirds (64%) chose not to enroll.

Employees in firms that pay most or all of the premium for coverage were more likely to enroll in employer-sponsored health plans. Among Rhode Island employers in 1999, the large majority (79%) of employers offering coverage paid at least three-quarters of the cost of individual (employee-only) coverage, and 61% paid at least three-quarters of the

cost of family coverage. Among employees in firms where the employer share of both the individual and family premium is three-quarters or more, 84% enroll in their employers' plans, compared to 67% in firms where the employer share is lower. (Figure 2) Among employees whose employers offer only individual coverage, 64% were enrolled when their employers paid at least three-quarters of the premium, compared to only 40% where the employer share was less.

Discussion

Rhode Island workers are very likely to be employed in firms where employers offer health benefits to their employees. However, a substantial number of employees do not participate in the offered health plans because the circumstances of their employment render them ineligible or because they choose not to enroll. Lack of eligibility is the largest

barrier to enrollment, especially for part-time workers. Only slightly less numerous is the proportion of workers who elect not to enroll. The enrollment decision is often tied to the share of the premium the employee must pay.

Thus, employers make several decisions that affect their employees' likelihood of participating in their health plans. The decision not to offer group health coverage has received most attention from policy-makers to date, but it appears to affect far fewer employees statewide than decisions on eligibility requirements and on the employer's share of the health premium. Policy makers will need to address all of these barriers in attempting to decrease the number of uninsured working-age Rhode Islanders and their dependents.

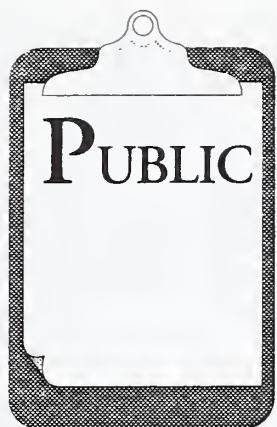
Acknowledgement

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Child Passenger Safety: A Major Problem for Bigger Kids

Nancy Libby Fisher, MMHS

Traffic crashes are the leading cause of death for children of every age from 6 to 14 years. A major cause of these deaths are children who are unrestrained or improperly restrained in vehicles.

Safety belts and child safety seats have been proven to save lives and prevent injuries. Although 97% of children from birth to one year of age and 91% of those 1 - 4 years of age use child safety seats, only 6.1% of children who should be in booster seats (about 4 to 10 years of age) are appropriately restrained.

Automobiles and adult safety belts are made for the comfort and safety of adults, not for children. Until children weigh about 80 pounds and are about 4 feet 9 inches in height, the safety belt restraint system will not fit them correctly. In car crashes, safety belts are designed to restrain adults at the strongest points of their bodies - across the hips and upper thighs and across the chest. For most children between 4 and 10 years of age, safety belts fit across the stomachs and lie against their necks. In collisions, the internal organs and the head and neck can be seriously injured.

Even the most safety-conscious parents are often not aware of the need for booster seats or the danger their children face when improperly restrained in an adult seat belt.

Rhode Island law requires proper restraints for children up to the age of four, and requires them to ride in the back seat through the age of five. The law does not require proper restraints for those 4 - 10 years of age when they have outgrown most child safety seats, yet are still too small to fit correctly into an adult safety belt. Most parents adhere to the law, believing that it represents safe practice.

Even with a suggested age range and height criteria for using booster seats, there are some children who meet this criteria who may not fit correctly in a safety belt. To decide when a child is ready for a safety belt, SafetyBeltSafe U.S.A. offers this 5-step test:

1. Does the child sit all the way back against the auto seat?
2. Do the child's knees bend comfortably at the edge of the auto seat?
3. Is the lap belt below the tummy, touching the thighs?
4. Is the shoulder belt centered on the shoulder and chest?
5. Can the child stay seated like this for the whole trip?

If the answer is "no" to any of these questions, the child needs a booster seat to ride safely in the car.

There are three basic types of booster seats - shield booster, backless belt-positioning booster, and high-back belt-positioning booster. The shield booster is used with the lap belt only, usually for a child between 30 and 40 pounds.

The highback booster seat must be used with lap and shoulder belts. The lap belt fits across the hips or upper thighs and the shoulder belt fits across the center of the chest. Some seats that are forward facing only have a harness. The harness is for a child who weighs 40 pounds or less. Once the child has outgrown the harness, then it is removed and the seat becomes a booster seat.

A highback booster is needed to prevent whiplash if the auto seat has a low back. If the backseat of the auto has a high back, then a backless booster seat may be used. Again, this seat positions the shoulder belt across the chest and the lap belt across the hips or upper thighs.

A booster seat is easy to use, but the shoulder belt should never be placed behind the back or under the arm, and any seat manufactured more than 10 years ago should be replaced.

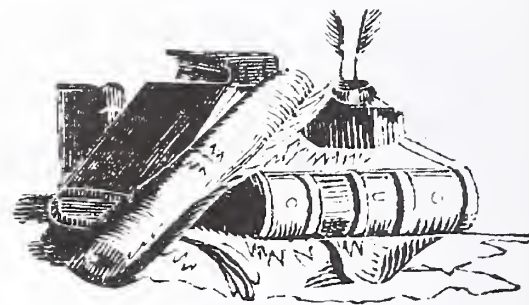
The Rhode Island SAFEKIDS Coalition has produced a brochure to educate parents and other caregivers about booster seat use. The brochure is distributed through day care centers and early childhood education programs and is available by calling the Department of Health at 222-4420. The Department is the lead agency for Rhode Island SAFEKIDS.

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2. SafetyBeltSafe, U.S.A. *The 5-Step Test*. Altadena, CA: SafetyBeltSafe, U.S.A., 2000.

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BOOK REVIEWS



Conservative Management of Cervical Spine Syndromes

by Donald R. Murphy, DC

New York: McGraw-Hill, 2000. 747 pages

When I was asked to review this text, my first reaction was one of concern. As a neurologist, skepticism is virtually obligatory when assessing chiropractic approaches to disease. My personal experience during residency with a patient who developed spastic quadriparesis after cervical chiropractic manipulation is vividly brought back to mind whenever I see a patient with cervical complaints who received chiropractic treatment. There are also reports of posterior circulation ischemia associated with cervical manipulation. Thus my approach to this text was with a critical eye; all the more reason for me to be pleased with what I discovered: a comprehensive text with an emphasis on differential diagnosis and institution of safe, interdisciplinary interventions.

Part I is a discussion of the basic science of the cervical spine starting with functional anatomy, biomechanics, and neurophysiology. These chapters are thorough and well referenced, and are made quite readable with the addition of schematic but very useful illustrations. The text is made more readable and interesting by references to personal experience. Discussions of the epidemiology and pathophysiology of cervical spine disorders round out the basic science portion.

Part II is devoted to clinical syndromes. The first two chapters discuss the consequences of motor vehicle crashes. The author begins with a compelling introduction correctly arguing that physicians usually have limited, if any, formal education in the diagnosis and management of traumatic injuries due to motor vehicle crashes. The chapters emphasize the "fundamentals," including the importance of mechanism of injury. The author deals directly with the issues of pre-existing complicating conditions, differential diagnosis of mechanisms of whiplash pain, as well as a discussion of potential mechanisms of visual auditory and vestibular symptoms. Precise definitions for loosely used terms such as strain, sprain, and spasm are provided. The author argues that litigation is not as much a factor in chronic pain as many American clinicians believe. This reader was not fully convinced but references are provided for further reading on the issue. These chapters provide a solid structure for the study of traumatic cervical spine injuries that I have not come across in other medical or neurological literature.

The next chapter in part II offers a detailed discussion of headache but with less emphasis on cervicogenic head-

ache than I had expected. The chapter on cervicoradiculopathy is thorough and nicely illustrated again with an emphasis relating mechanism to symptoms and treatment. Particularly important is the fairly extensive discussion of "red flags" on examinations, which could suggest that urgent invasive intervention may be required rather than simply conservative management. A nice discussion of the utility of electrodiagnosis with EMG and nerve conduction studies is included.

There are a few examples in the book of authors describing treatments based on their "own experience," but without clear supporting medical literature. For example, the discussion of treatment options is quite complete but I was struck by the statement that "although its efficacy has not been clearly demonstrated, cervical traction is often useful." On the other hand I think one would be hard pressed to find a clinician who does not utilize his own experience in addition to scientific literature.

The section on clinical syndromes concludes with "neuropsychological dysfunction related to cervical trauma," a very interesting discussion of cognitive symptoms in the setting of cervical cord injury with proposed mechanisms. Secondary factors (which may actually take on a primary role) including sleep disorders and medication effects are discussed.

Part III consists of extensive discussions of history, examination and diagnostic imaging. I was impressed to find a chapter on outcomes management. Many measurement tools are included although most suffer from being quite subjective, and dependent on self-reporting. These weaknesses are discussed, not ignored, and put into context.

Part IV includes several chapters regarding treatment with an emphasis on cervical chiropractic manipulation. The discussion of what actually happens during manipulation is extensive but includes terms unfamiliar to the allopathic physician making a good part of the discussion unclear to this reader. The potential for vertebral artery compromise (a rate of one occurring out of every 1 million manipulations is mentioned) is discussed but a potential for cervical cord compression is not. Contraindications to cervical manipulation are described including vertebral fractures, inflammation, dislocation, malignancy, and pre-existing myelopathy, among others.

Vertigo and unsteadiness are mentioned both as symptoms that may accompany cervical spine pathology and as

red flags for potential vertebrobasilar ischemia. It is not clear to me how or when one decides to proceed with cervical manipulation in the presence of these symptoms. The risks are acknowledged but are felt to be low and can be reduced by not manipulating high-risk individuals. Case studies are presented and the authors are not reluctant to provide examples of poor outcomes (most demonstrate that the practitioner failed to heed the warning signs).

Part IV concludes with a chapter on operative treatment of the cervical spine. The brief chapter provides a good overview of indications for surgical intervention and a few techniques are described.

Part V is a discussion of the role of rehabilitation medicine techniques in cervical spine syndromes. The techniques are clearly relevant and beneficial. The chapter devoted to the McKenzie protocol is extensive but again unfamiliar terminology is a barrier to full understanding of this approach.

The final section is simply titled "Management." This part includes 3 short chapters which may ultimately be the most useful in the book. They provide straightforward protocols for the approach to both simple and more complex cervical patients. The third is a discussion of psychological management as cervical syndromes can have a major impact on most aspects of life including interpersonal relationships and occupation.

In conclusion Dr. Murphy showed great care and skill

in the development of *Conservative Management of Cervical Spine Syndromes*. The text is comprehensive but not boring and often confronts controversial issues. A strong emphasis on patient education (not seen often enough in medical texts) is present. "Clinical pearls," which stand out from the text, are another nice feature. They include clinically useful statistics as well as interesting clinical observations. I particularly admired the interdisciplinary approach both in the content of the chapters and in the selection of the authors. Practitioners of many disciplines including internists, chiropractors, neurologists, physiatrists, orthopedists, neurosurgeons and therapists will find this book a useful and refreshing addition to their spinal disorder library.



– Reviewed by Stephen T. Mernoff, MD

Stephen T. Mernoff, MD, is Clinical Assistant Professor of Neurology, Brown University School of Medicine, and a neurologist at Roger Williams Medical Center and Rehabilitation Hospital of Rhode Island.



Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report

Provisional Occurrence Data
from the
Division of Vital Records

Underlying Cause of Death	Reporting Period			
	December 1999	12 Months Ending with Dec. 1999		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	317	2,997	303.2	4,178.0
Malignant Neoplasms	231	2,484	251.3	6,892.0
Cerebrovascular Diseases	52	539	54.5	619.5
Injuries (Accident/Suicide/Homicide)	30	380	38.4	6,923.0
COPD	47	501	50.7	407.5

Vital Events	Reporting Period		
	June 2000	12 Months Ending with June 2000	
	Number	Number	Rates
Live Births	1,011	12,933	13.1*
Deaths	756	10,029	10.1*
Infant Deaths	(7)	(103)	8.0#
Neonatal deaths	(6)	(86)	6.6#
Marriages	962	7,909	8.0*
Divorces	279	2,918	3.0*
Induced Terminations	428	5,182	400.7#
Spontaneous Fetal Deaths	61	1,136	87.8#
Under 20 weeks gestation	(51)	(1,063)	82.2#
20+ weeks gestation	(10)	(73)	5.6#

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 988,480

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population

Rates per 1,000 live births

NINETY YEARS AGO

❧ [DECEMBER, 1910] ❧

In "The Parent's Duty to Instruct His Son in Sexual Hygiene," W.H. Peters, MD (a member of the American Society of Sanitary and Moral Prophylaxis) argued that sexual repression came with civilization: "Barbarism, savagery, has no such problem. Among savage people the sexual passion begins to be indulged freely immediately the individual becomes sufficiently mature to feel the...instinct." Marriage was the hallmark of civilization, but Dr. Peters conceded that "marriage oftentimes, in fact generally, militates against the natural sexual instinct." A father should keep his son "continent until marriage," first by stressing the dangers of incontinence upon the men's future wives: a Medical Society of New York study found 30% of venereal disease in women treated in private clinics were caused by infection from their husbands; a 1907 Maryland State Medical Society found 40% of gonorrheal infection in women seen in private practice came from their husbands; Paris' Professor Fournier estimated that one in five cases of syphilis in women were traced to husbands. Second, the father should denounce the double standard: "Restraint harmful? Indeed it is not; on the contrary it makes for the strong and noble man." Finally, "marry your boy as early as possible."

Herbert Terry, MD, in "Drainage after Supra-Pubic Cystotomy," discussed the benefits of the procedure, admitting: "In my own experience those who have died ...have died from shock, uremia, or post-operative dementia, and the percentage of fatalities has not been very great. I do not think that any have died of sepsis, though I may have mistaken sepsis for uremia."

Albert Miller, MD, in "The Choice of the Routine Method for Administering Ether" traced the "lack of uniformity in methods of administering ether and the continued use of some very crude...methods" to

general ignorance about anesthesia. Clinicians lacked "a clear idea of the underlying physical and physiological laws."

FIFTY YEARS AGO

❧ [DECEMBER, 1950] ❧

In "Treatment of hypertensive vascular disease by sodium restriction," Michael DiMaio, MD, concluded: "Sodium restriction is not the answer to the treatment of hypertension," in part because of the "utter lack of palatability of all low sodium diets." Even when a patient has said s/he followed such a diet, Dr. DiMaio noted, "the patient's words must be taken with a grain of salt."

The Journal reprinted "Survival under Atomic Attack," from the Executive Office of the President, the National Security Resources Board, and the Civil Defense Office. The article advised: "In small amounts, radioactivity seldom is harmful." As for "Survival Secrets for Atomic Attack," the suggestions included: "Bury your face in your arms. Don't rush outside right after a bombing. Don't take chances with food or water in open containers. Close all windows and doors and draw the blinds."

TWENTY FIVE YEARS AGO

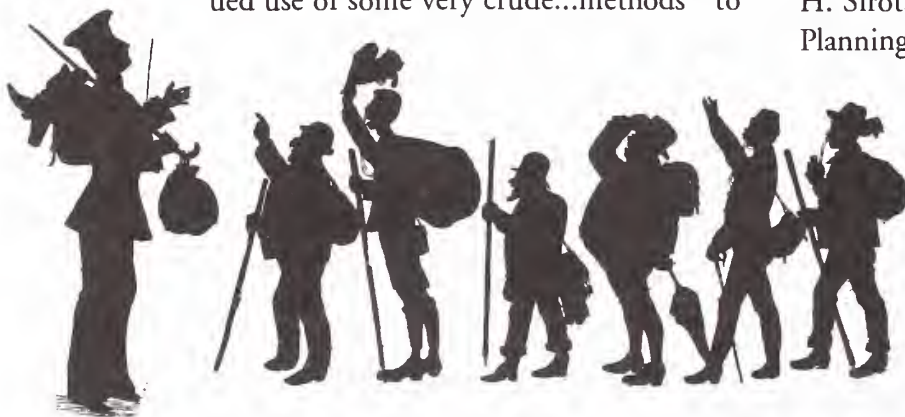
❧ [DECEMBER, 1975] ❧

In "Brown Medical faculty active in Significant Research," the Journal detailed the annual meeting of the American College of Physicians, held at Brown, with brief descriptions of the 16 presentations.

Milton W. Hamolsky, MD, in "Laboratory Tests of Thyroid Function," noted that, "Appropriate studies supplementing history and physical will provide a rational basis for diagnosis and treatment."

William J. Waters, PhD, Mary Pat Moore, MA, Stephen H. Sirota, MD, Neil Young, MA, in "Community Health Planning in Rhode Island Following the Navy's Withdrawal," linked the economic adversity to the deterioration of health and health services. They concluded that the military retirees and dependents were the most affected.

Susan Trachtenberg, a Brown undergraduate, contributed "When Medical Technology Fails: To allay the anxieties of the living and end life in dignity should be our goals."



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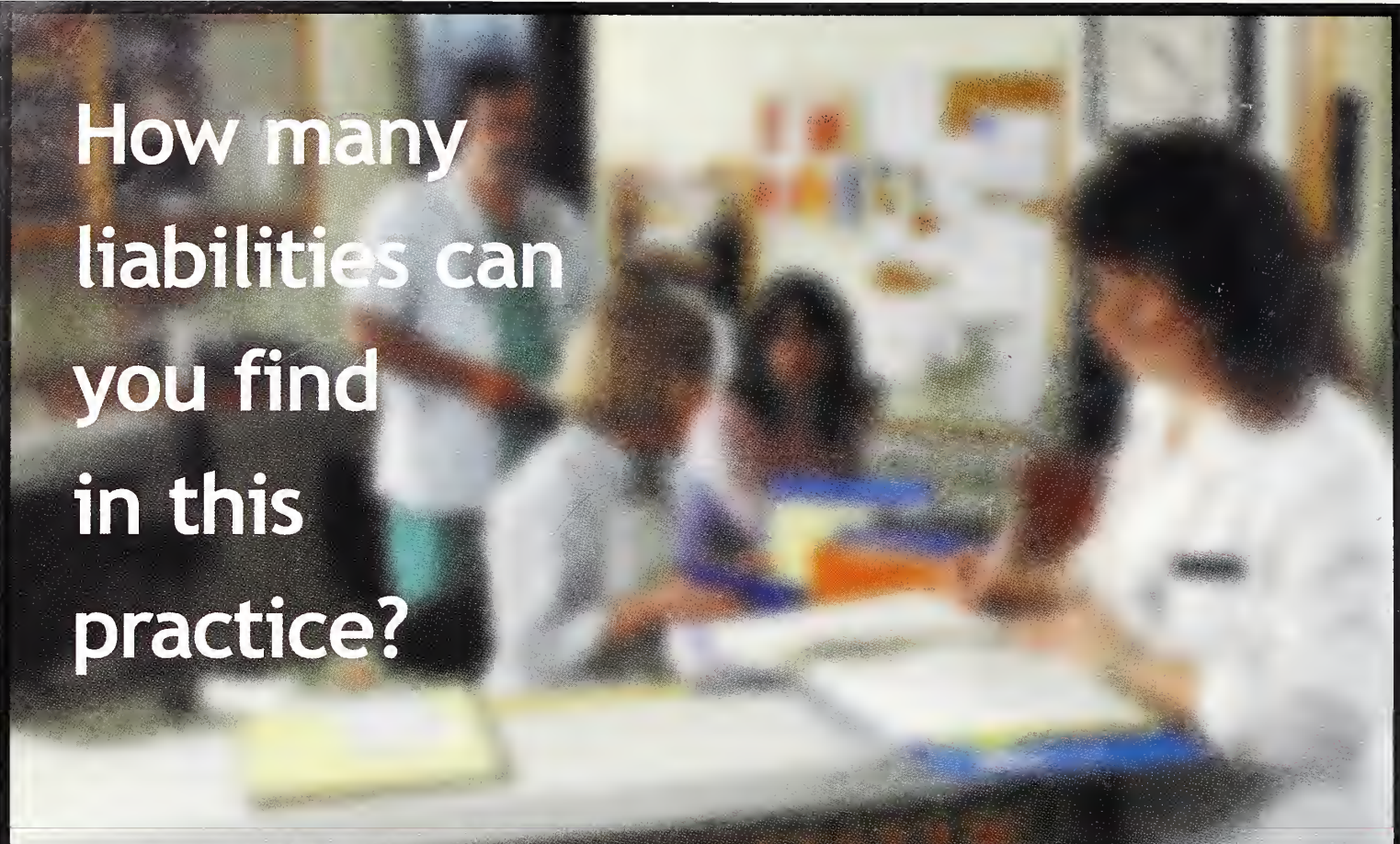
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